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(12) **United States Patent**
**Niese et al.**

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(54) **GRAFT FIXATION**

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(51) **Int. Cl.**

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USPC ..... 623/13.11–13.2; 606/232, 233, 228

See application file for complete search history.

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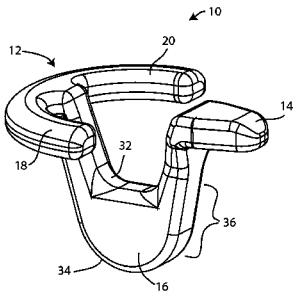
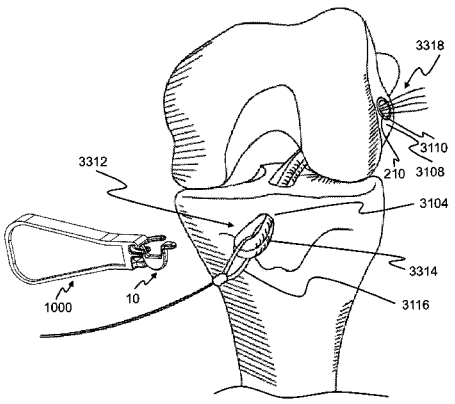
(57) **ABSTRACT**

A system for graft fixation including ACL graft reconstruction and fixation is presented. The system may comprise a loop fixation device for retaining a tissue graft. The loop fixation device may comprise a graft retention portion and a cortical fixation portion to allow the loop fixation device to rest on the cortical portion of a bone. A tissue graft may pass through a bone tunnel and engage the loop fixation device preventing withdraw of the tissue graft back through the bone tunnel. The system may also include graft fixation within a bone tunnel using a sleeve, or tube construct, with a fixation member, or screw, to engage a tissue graft within the sleeve.

**20 Claims, 41 Drawing Sheets**



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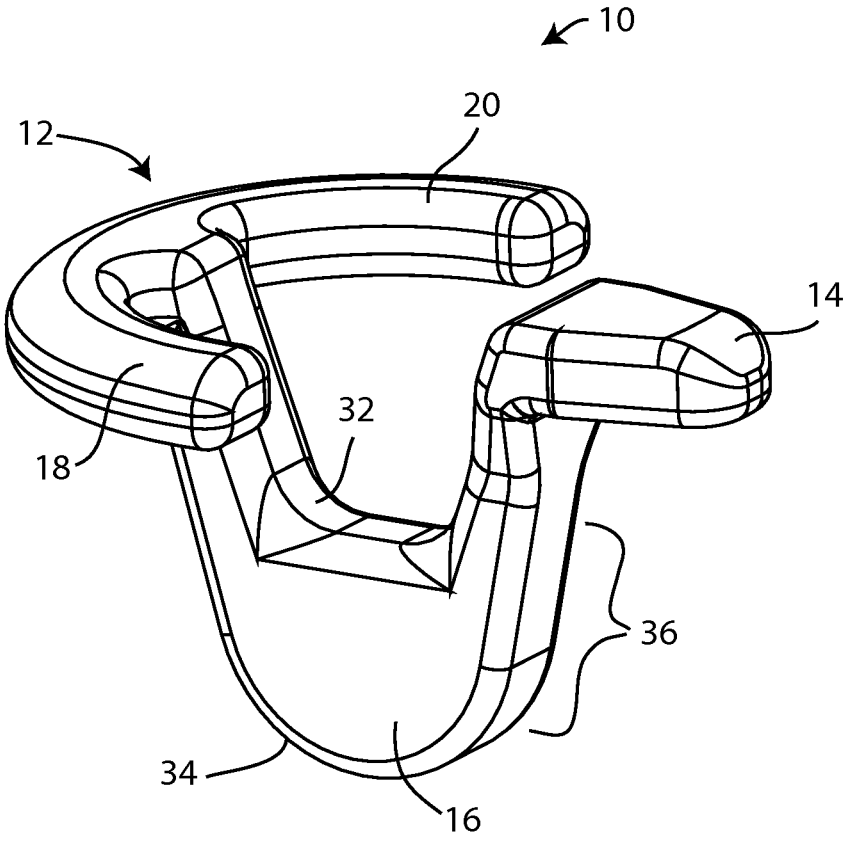


FIG. 1

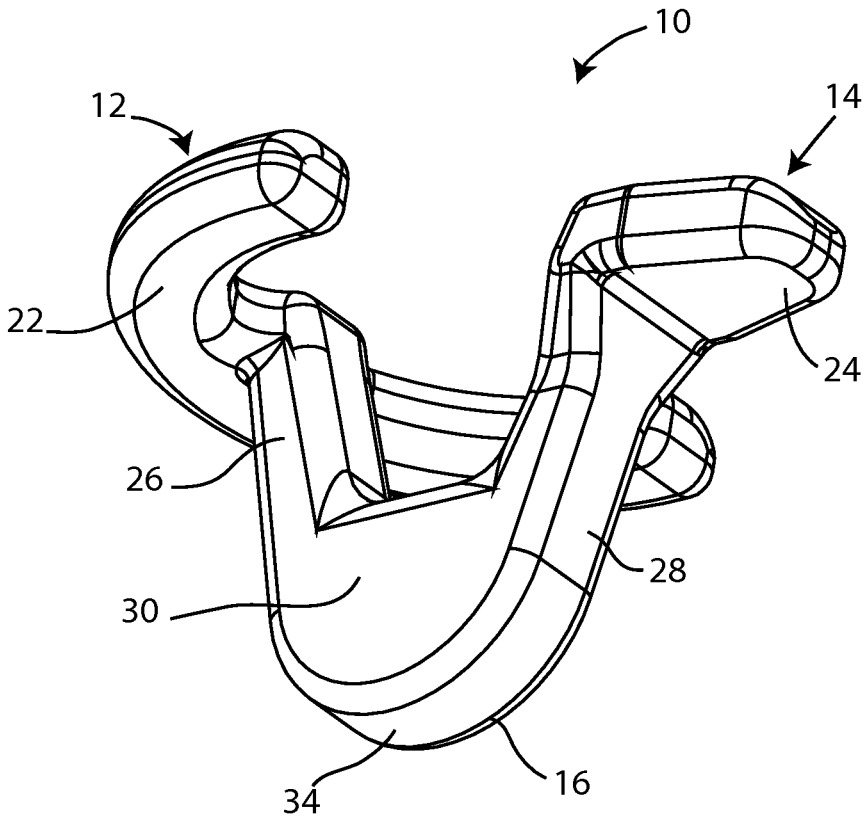


FIG. 2

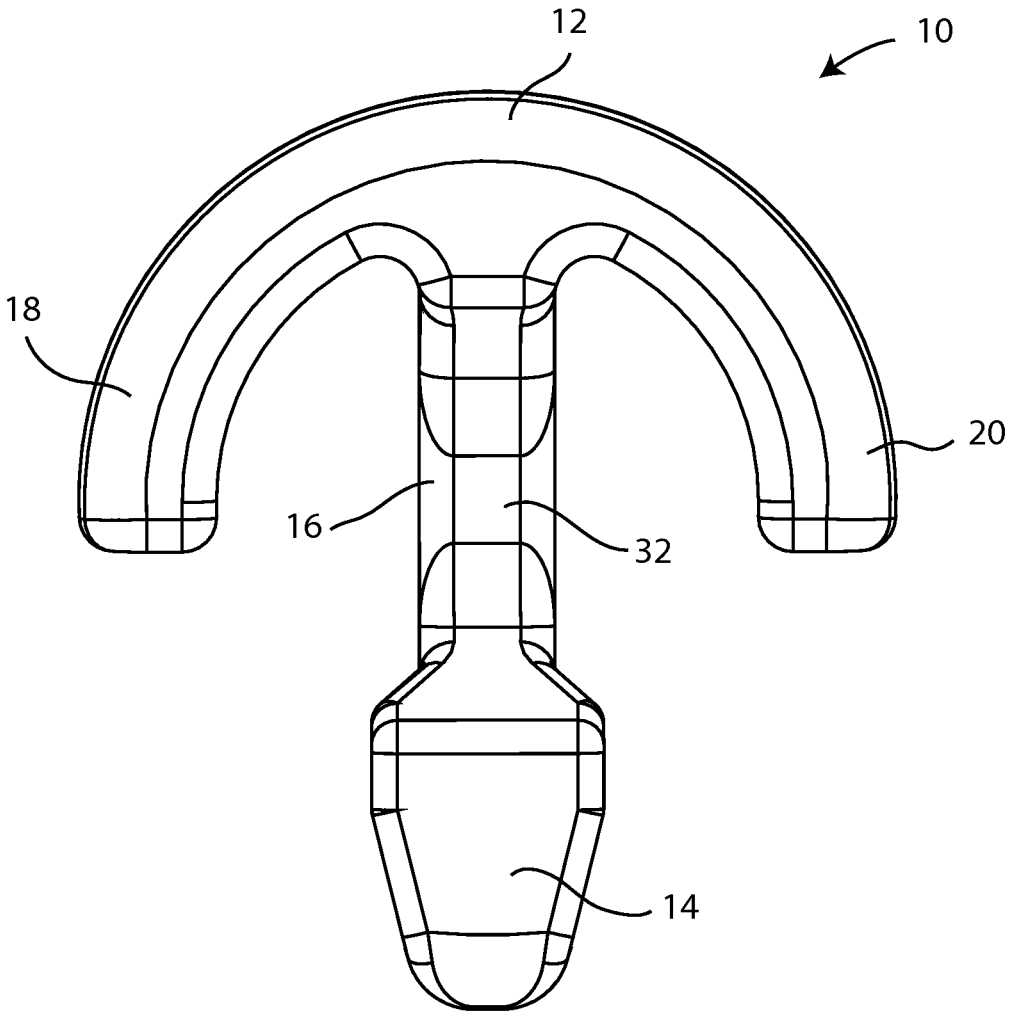


FIG. 3

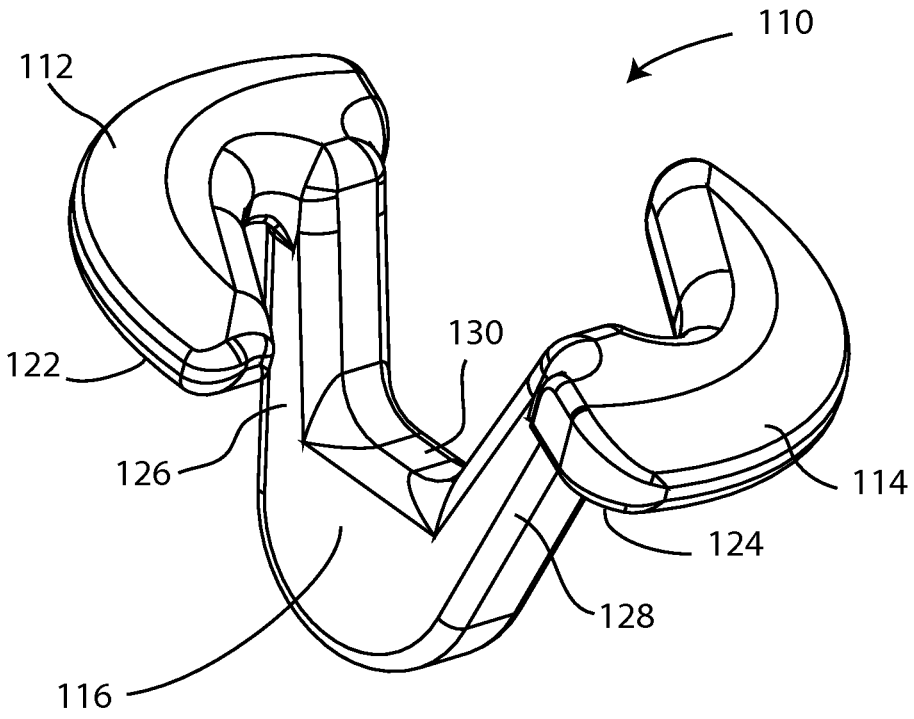


FIG. 4

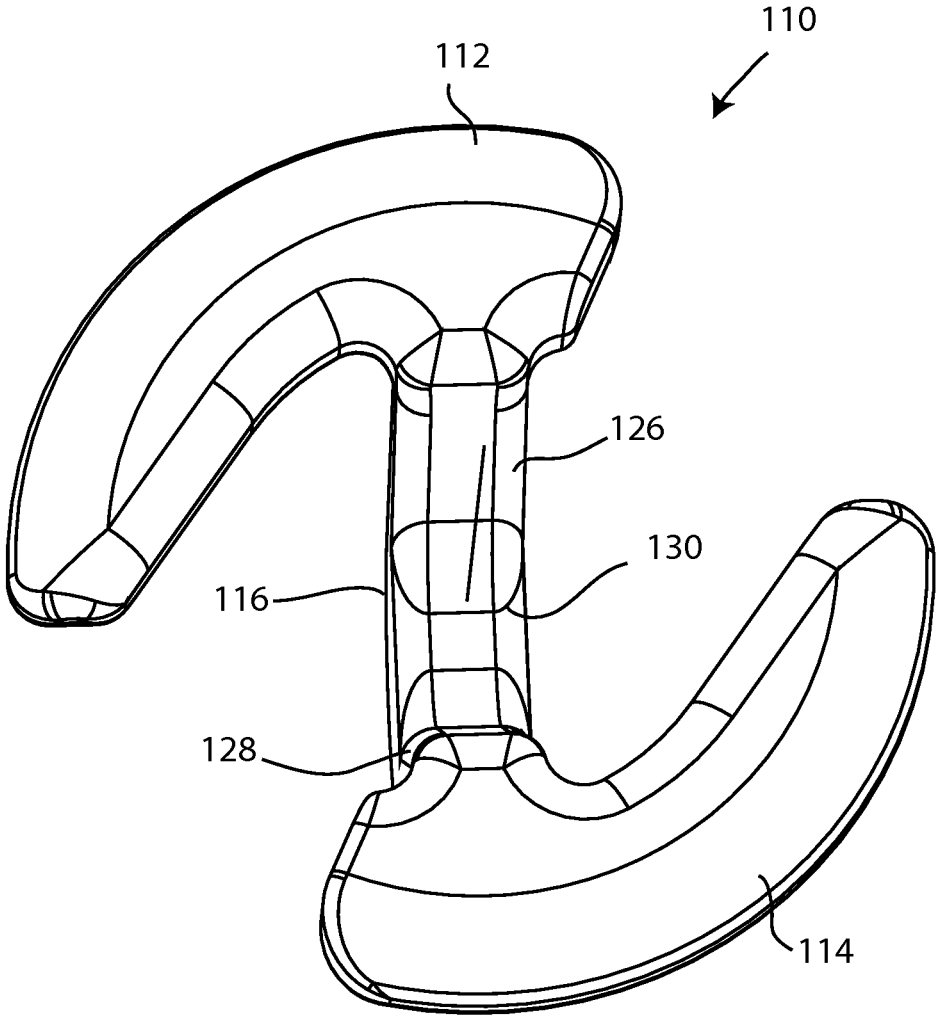


FIG. 5

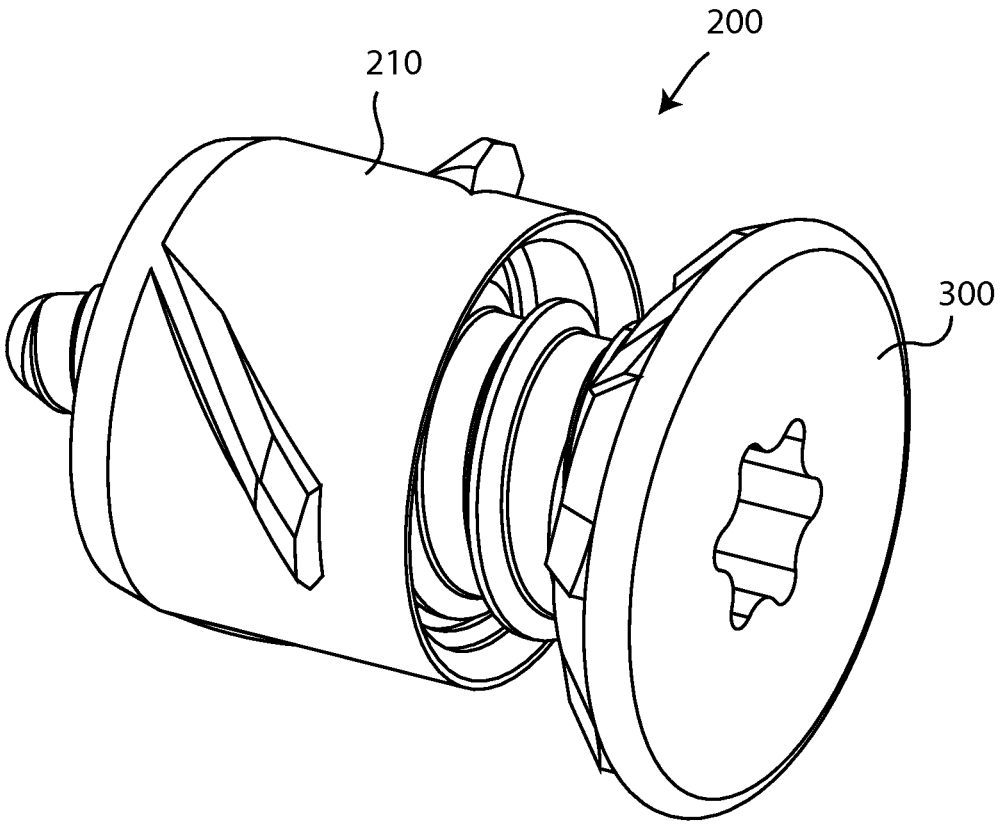


FIG. 6

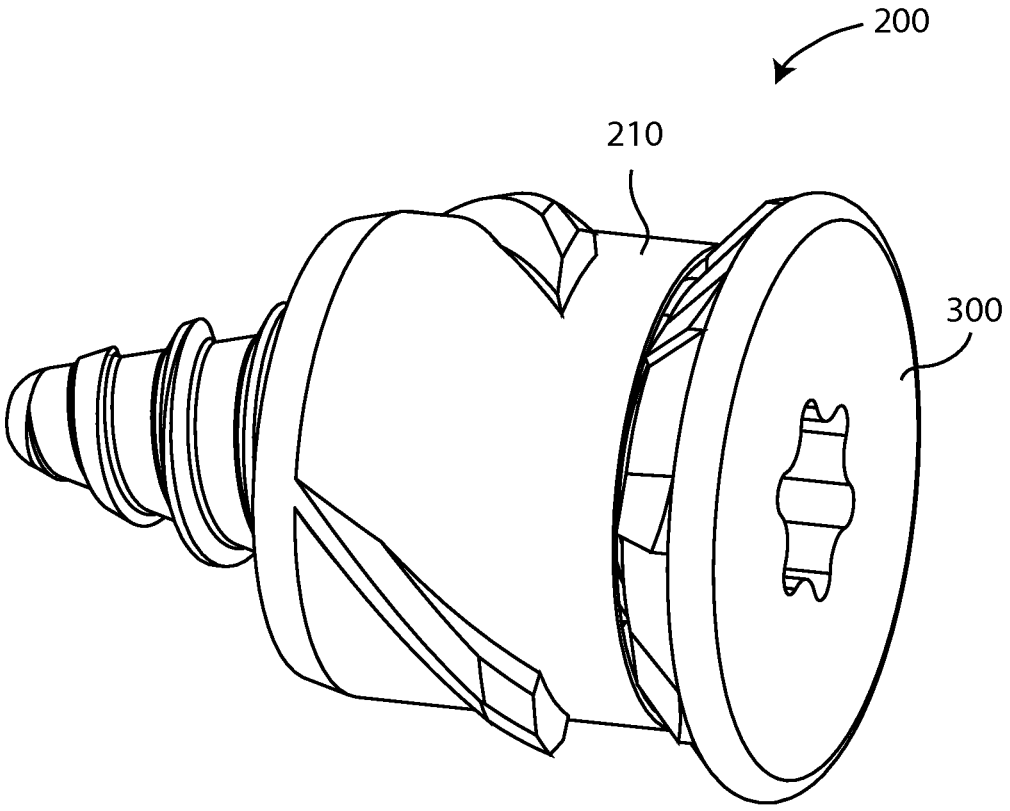


FIG. 7

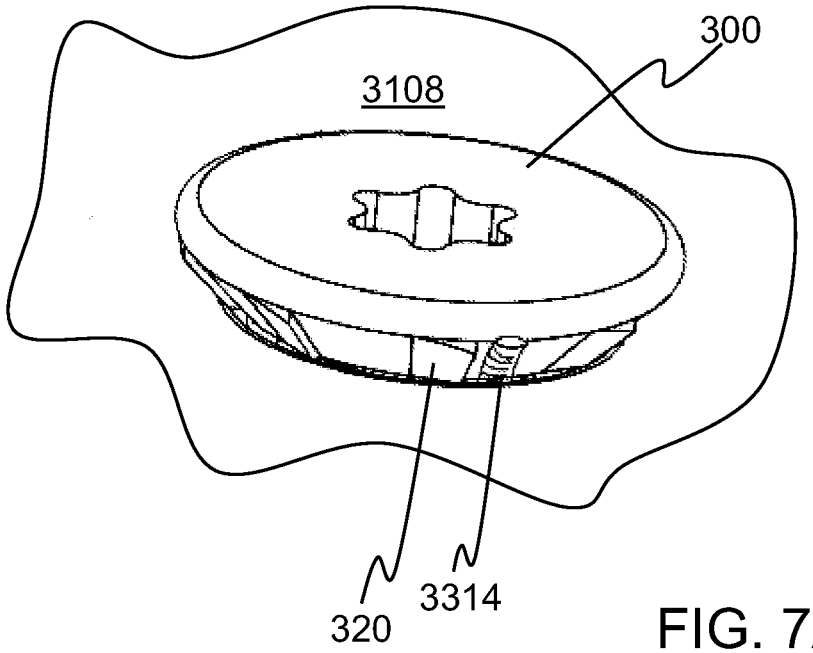


FIG. 7A

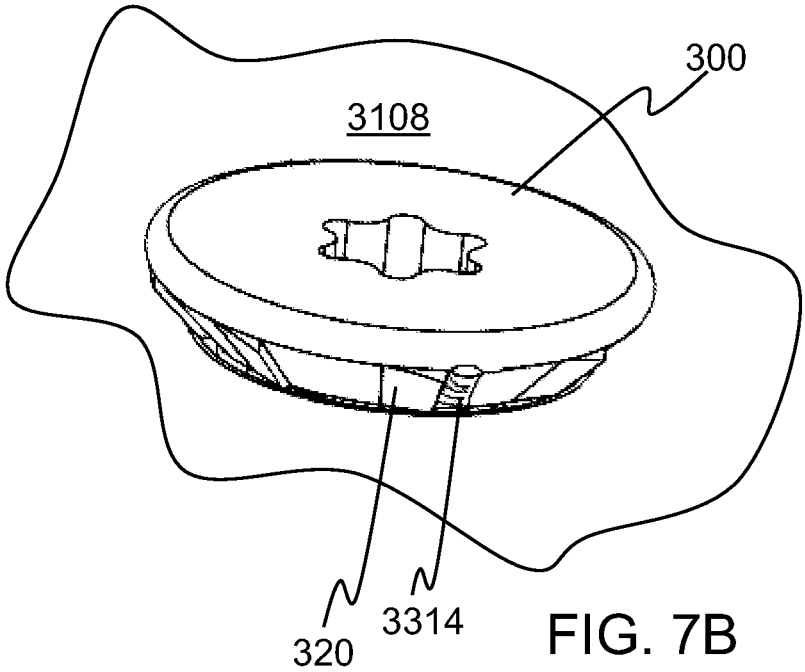


FIG. 7B

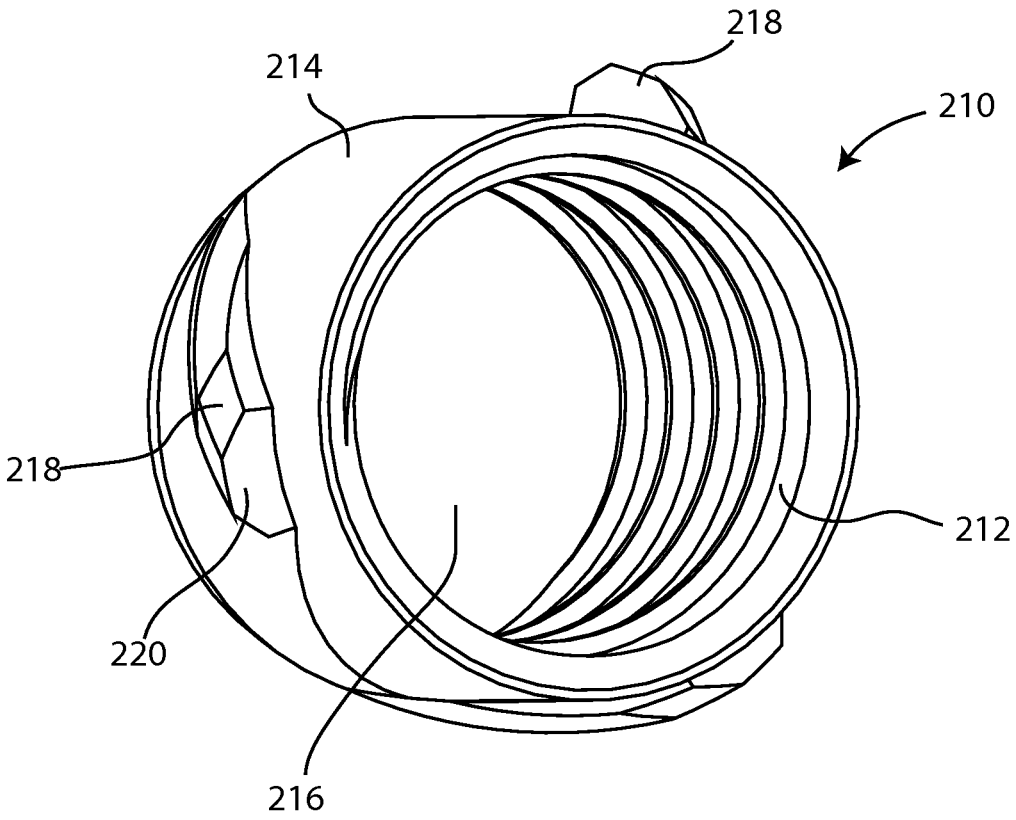


FIG. 8

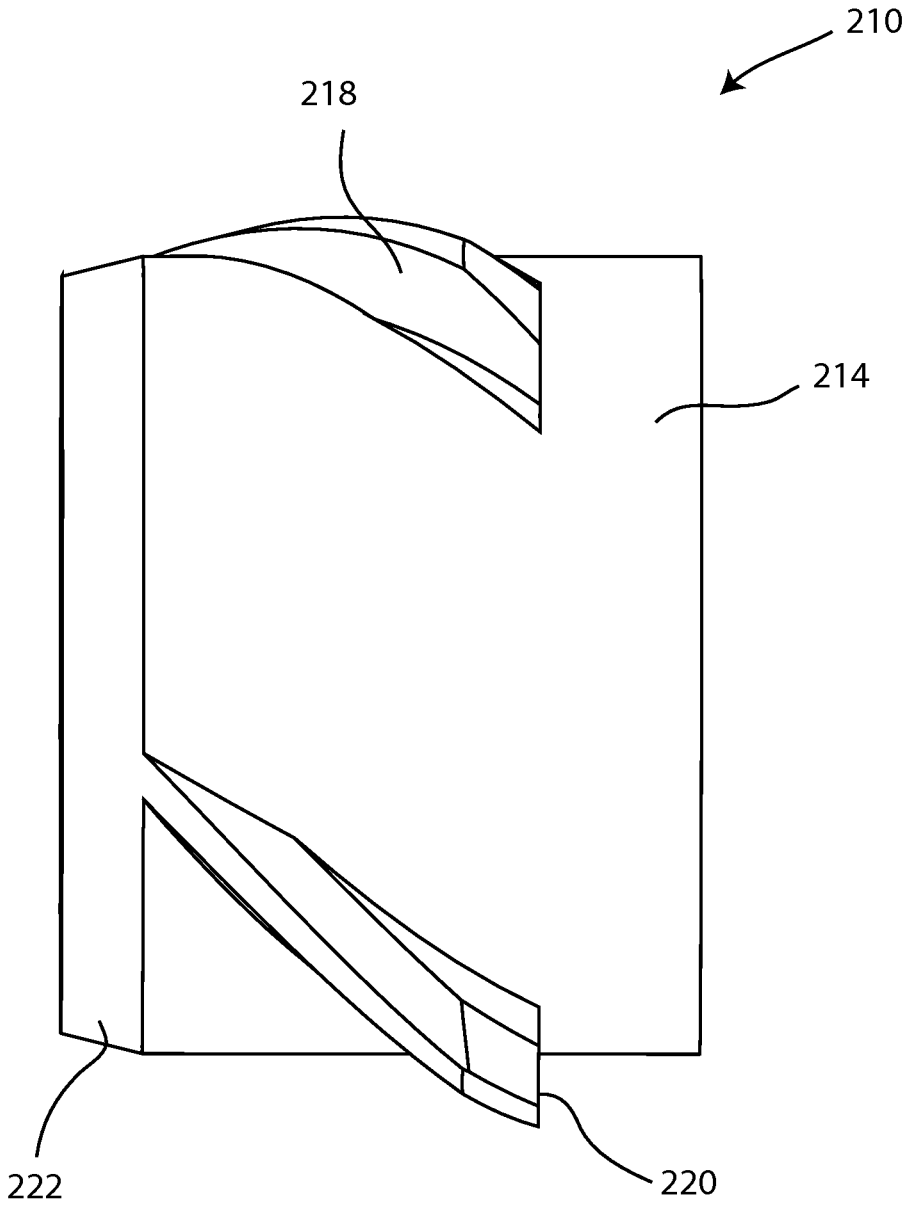


FIG. 9

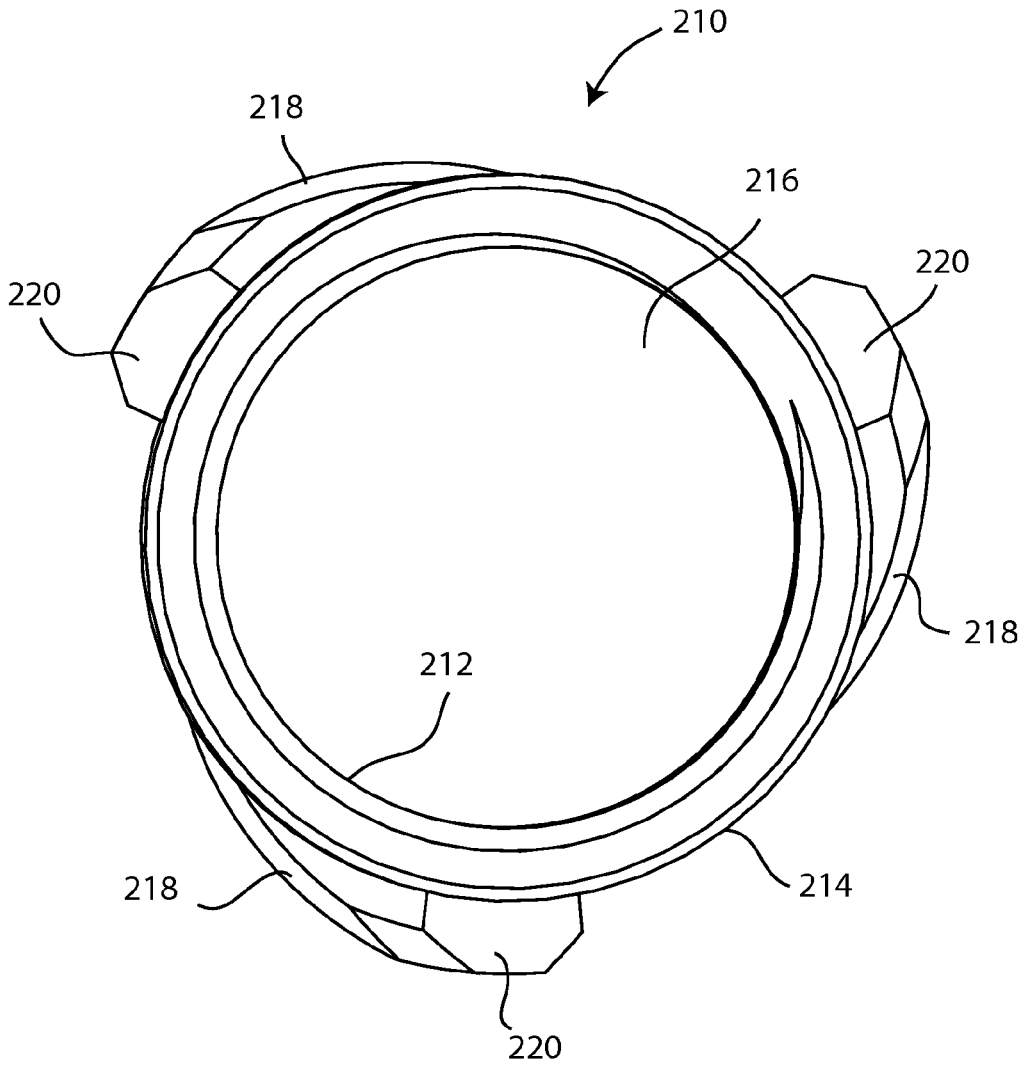


FIG. 10

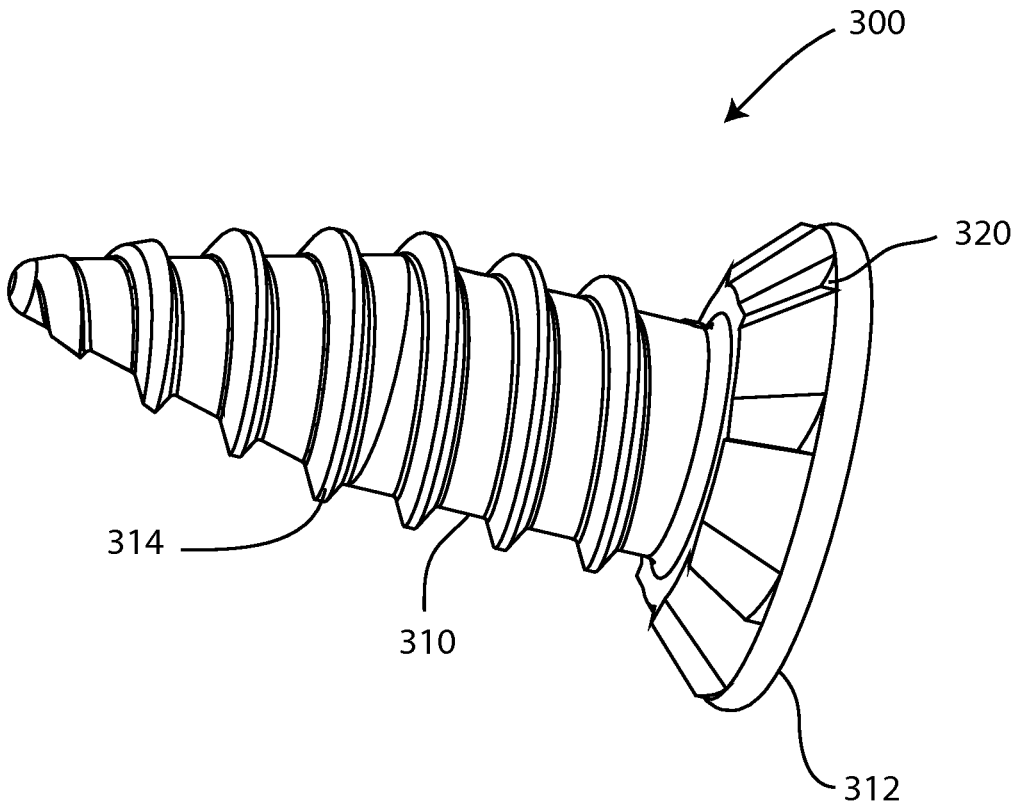


FIG.11

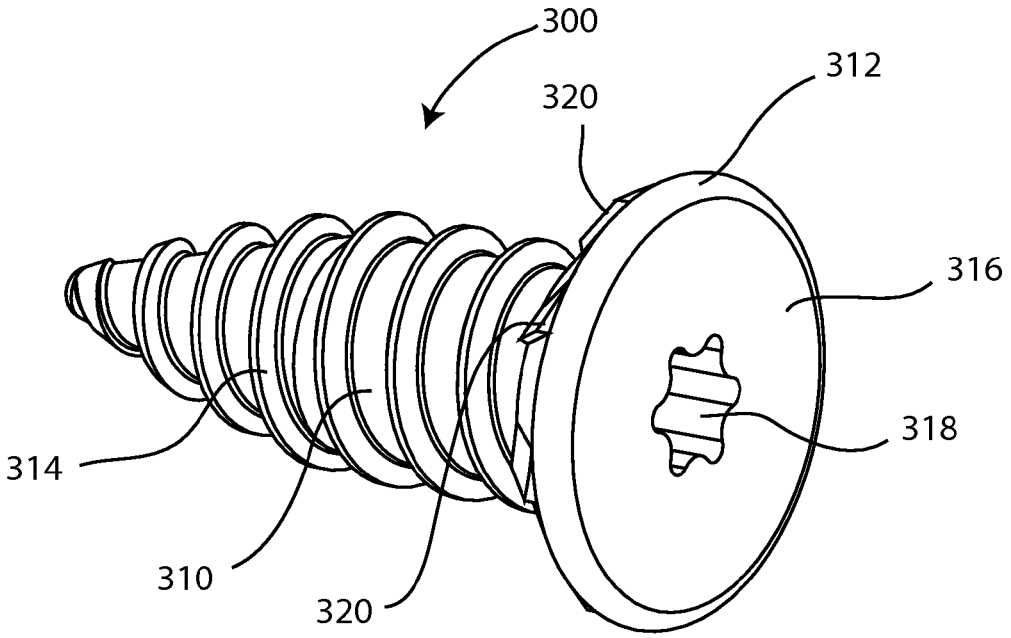


FIG. 12

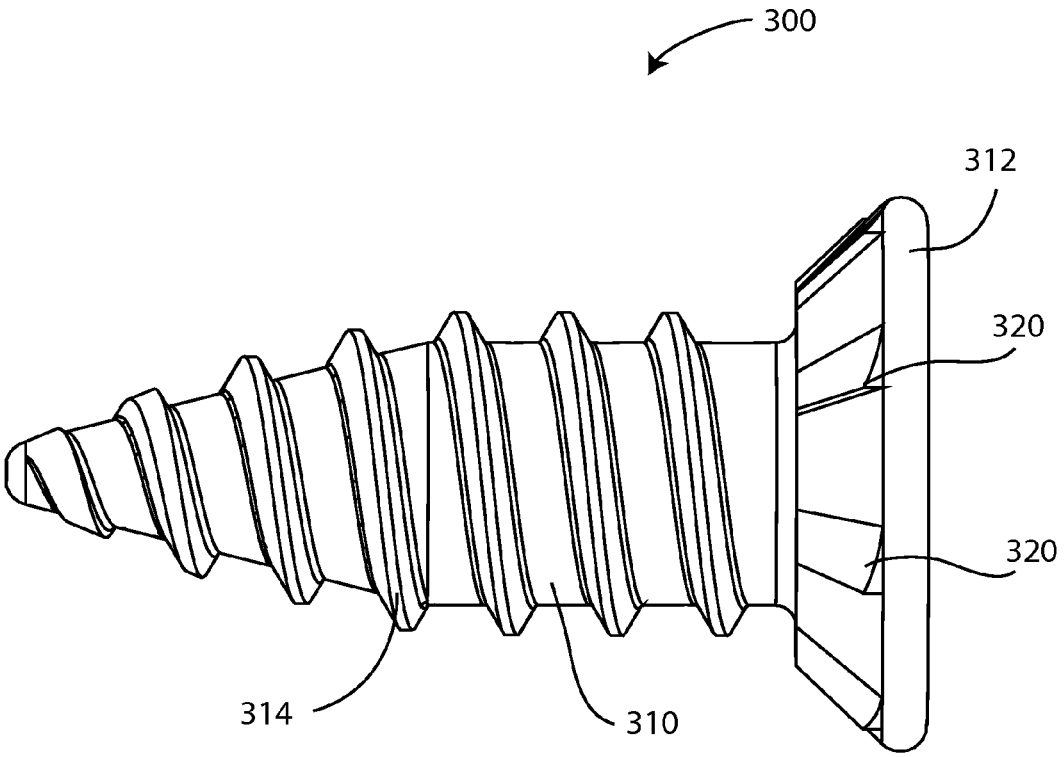


FIG. 13A

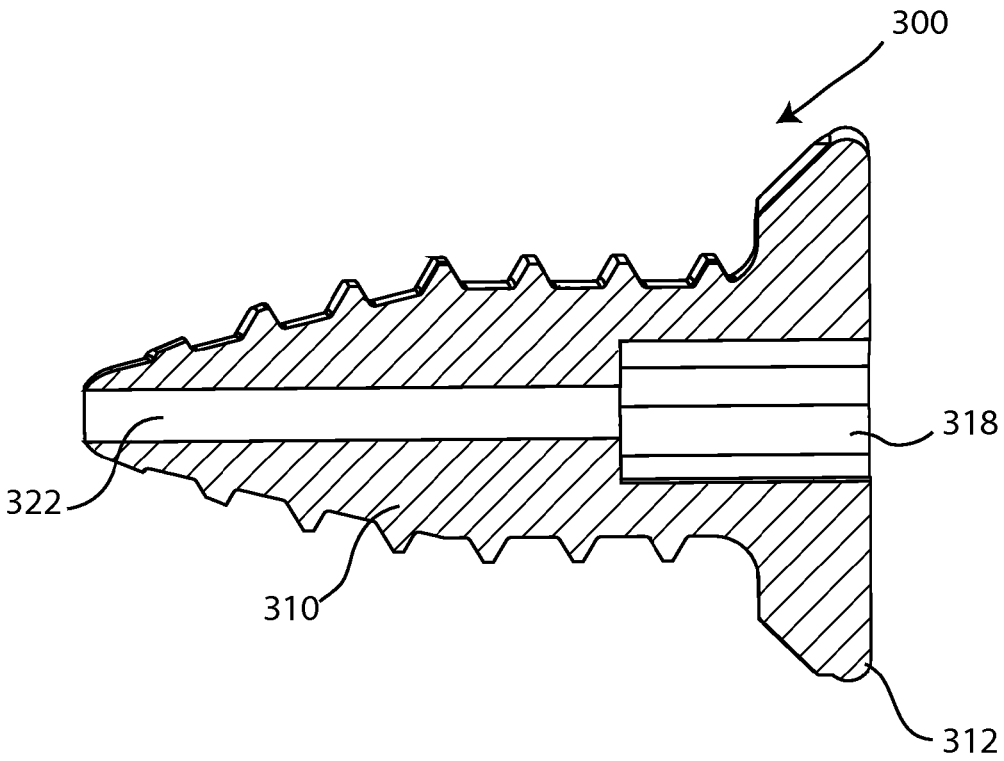


FIG. 13B

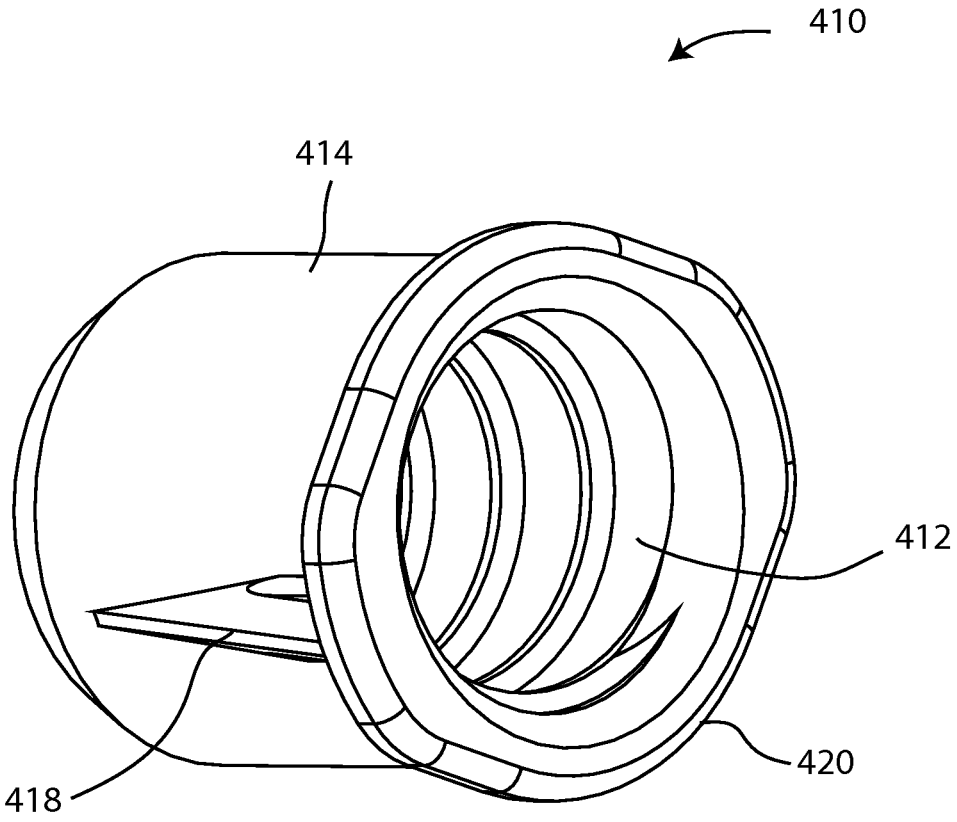


FIG. 14

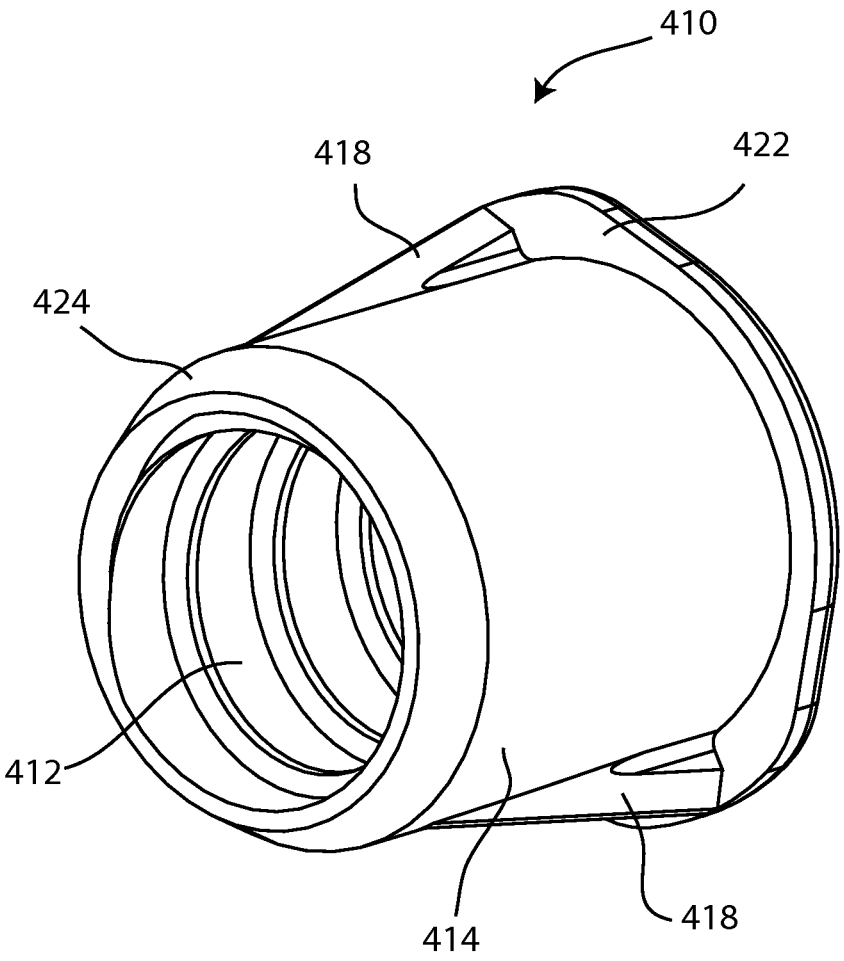


Fig. 15

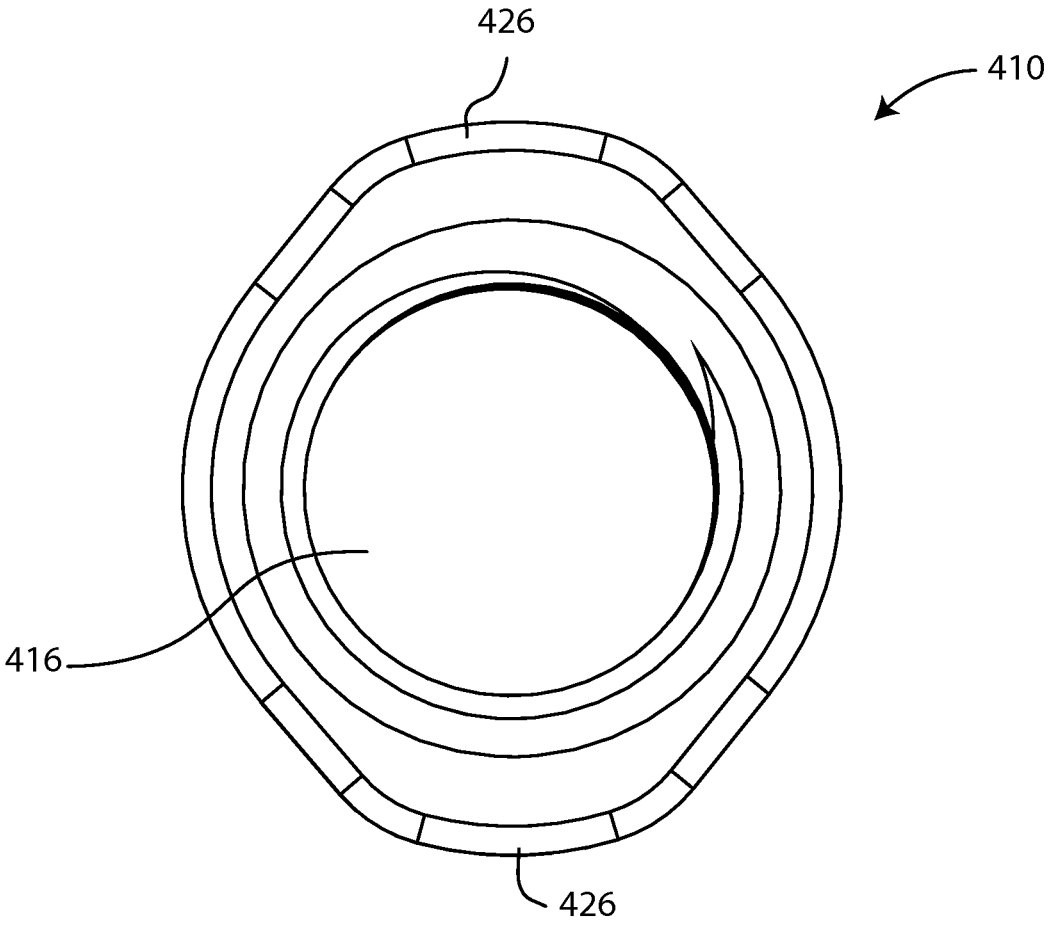


FIG. 16

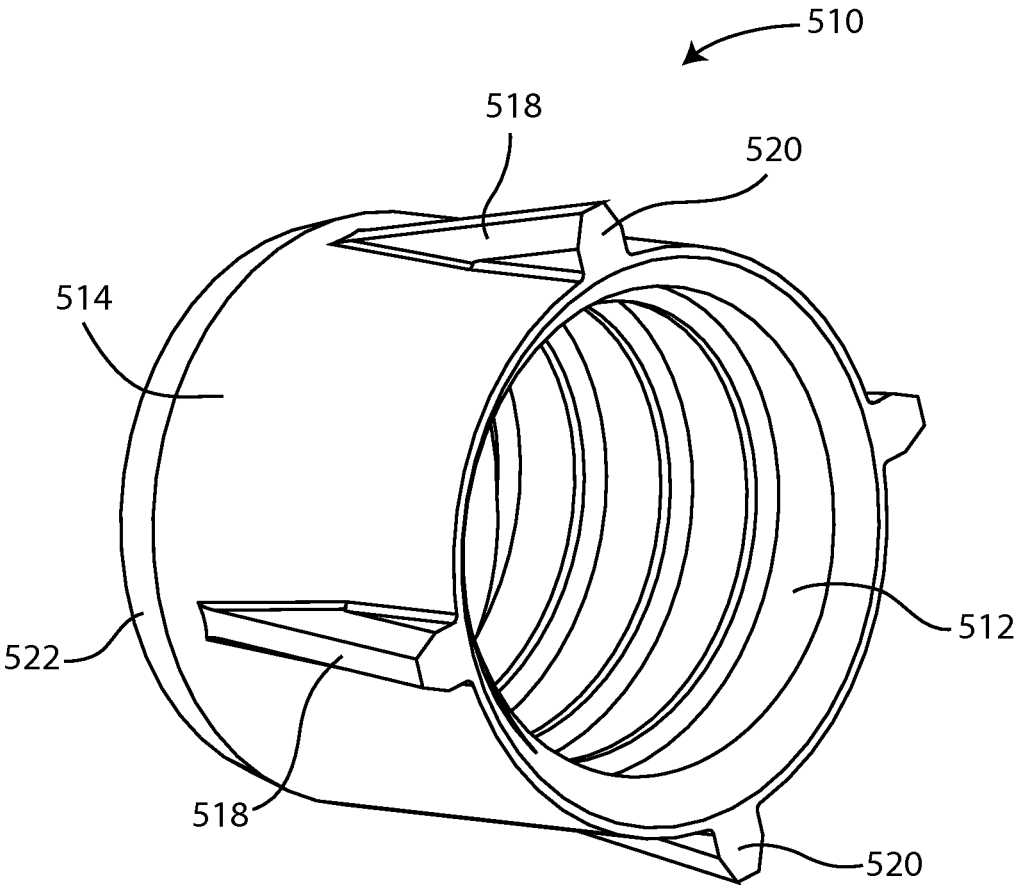


FIG. 17

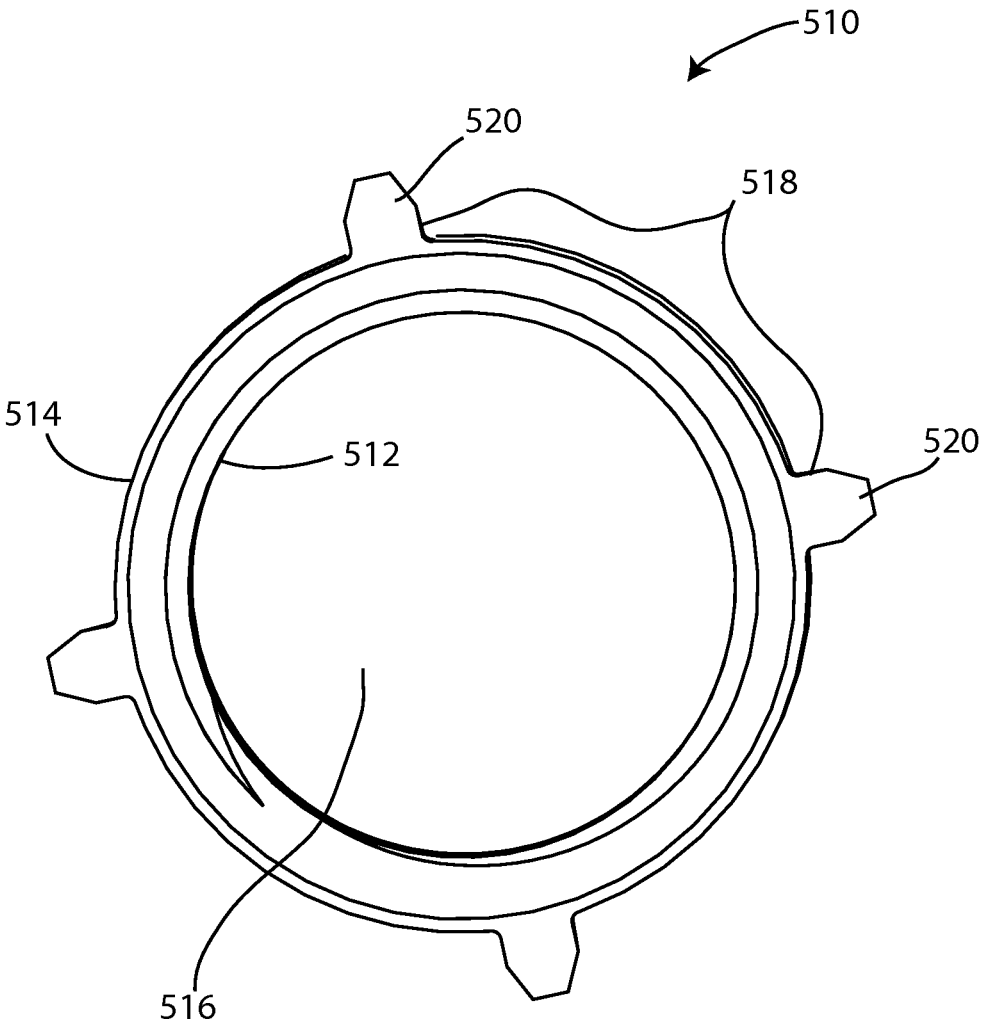


FIG. 18

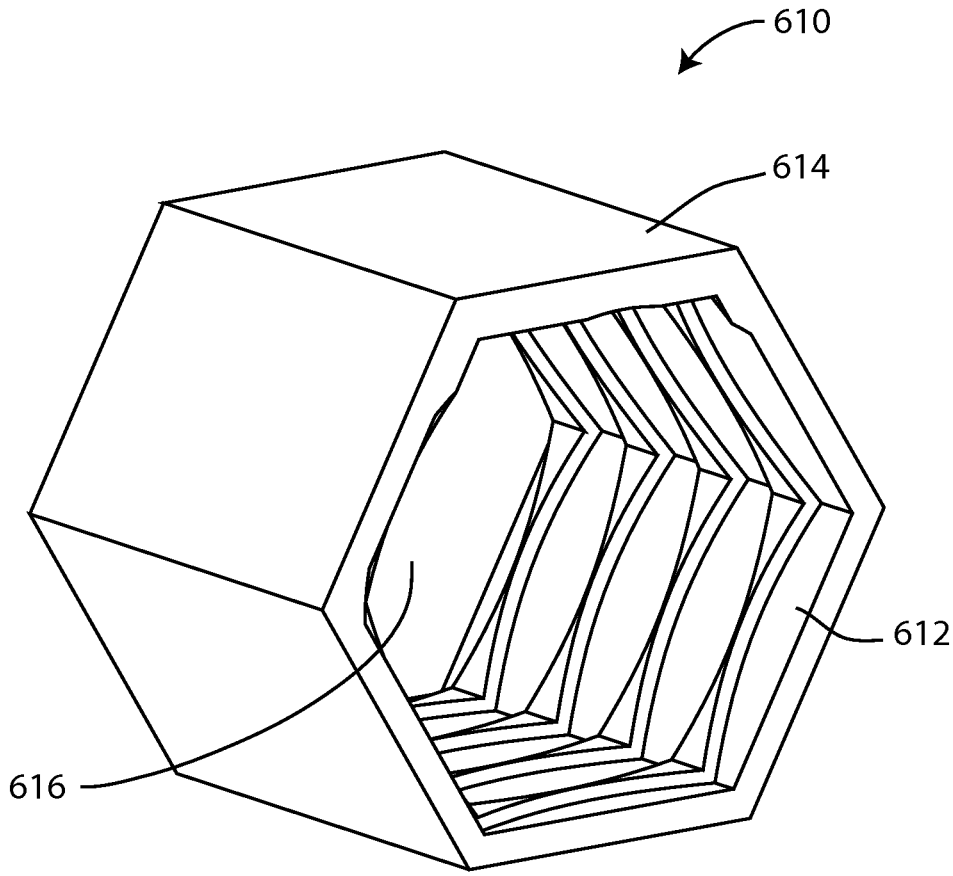


FIG. 19

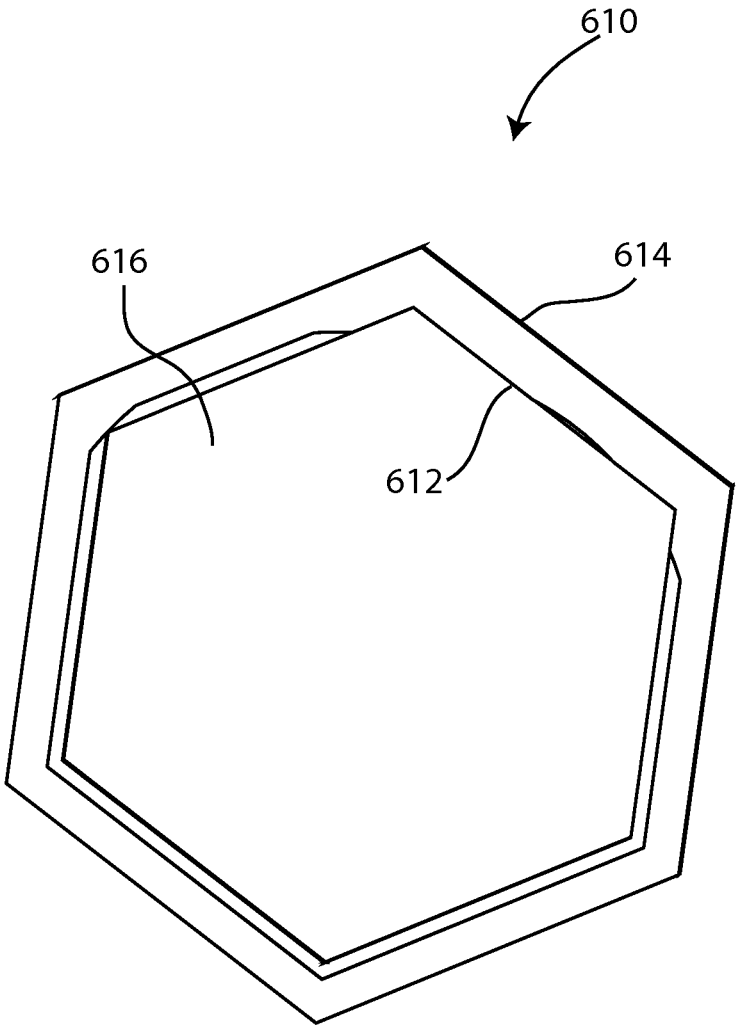


FIG. 20

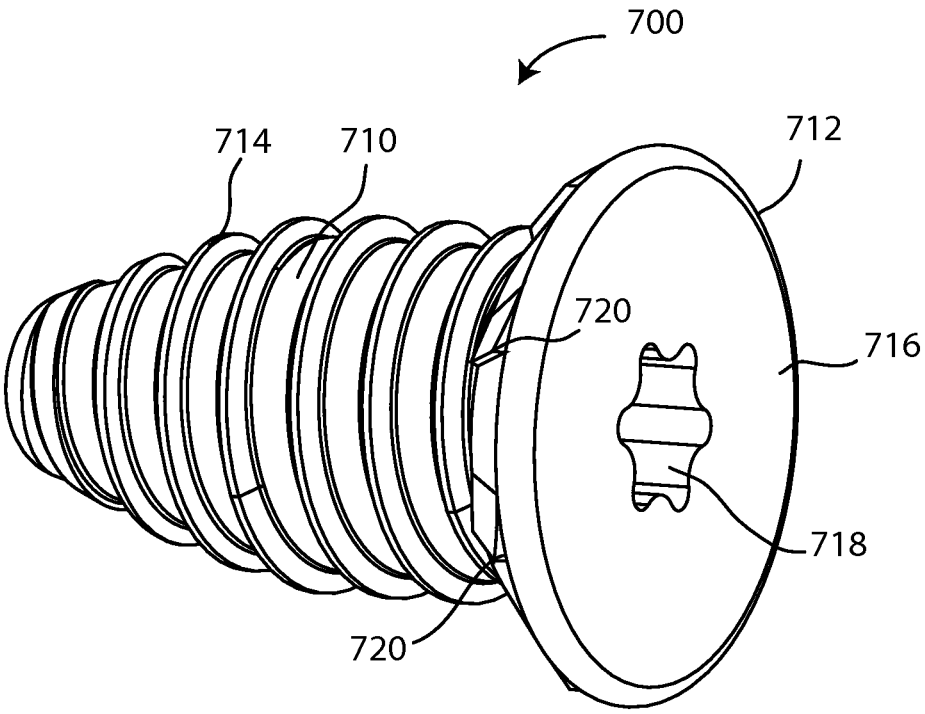


Fig. 21

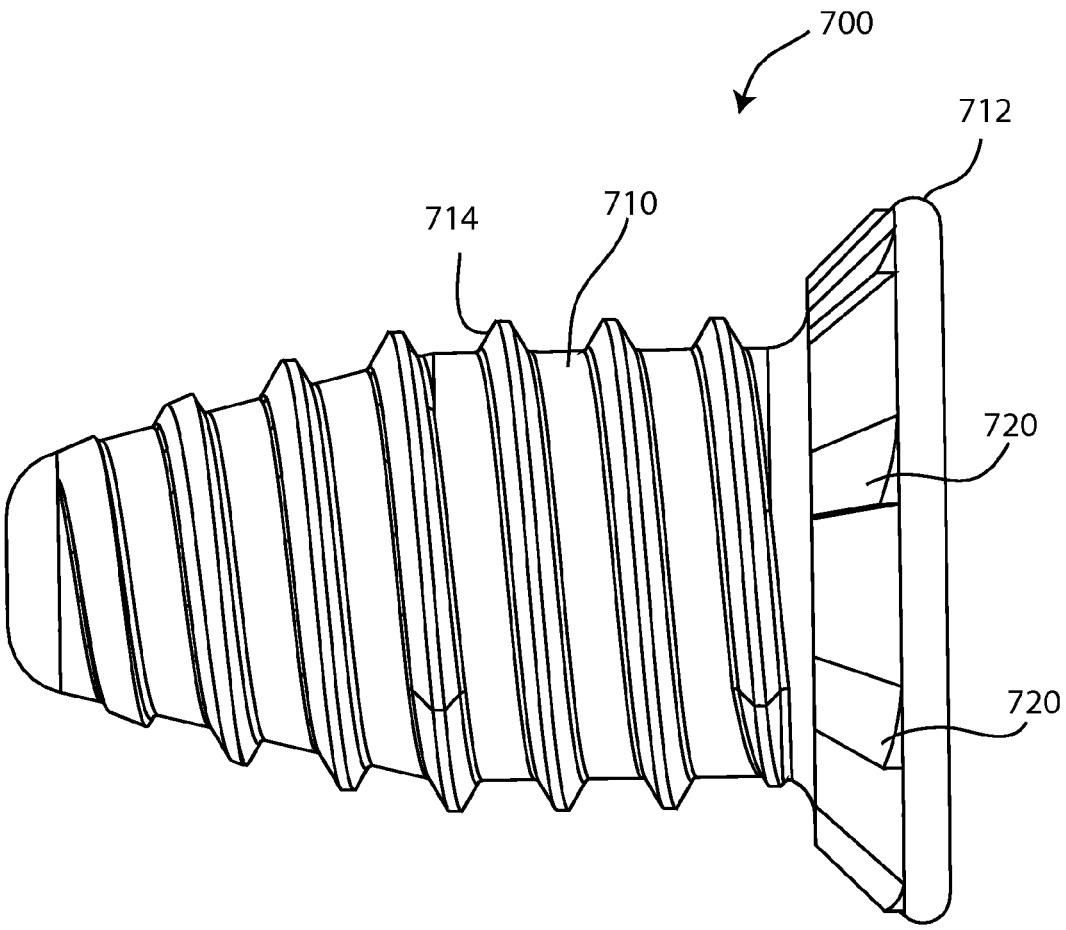


FIG. 22

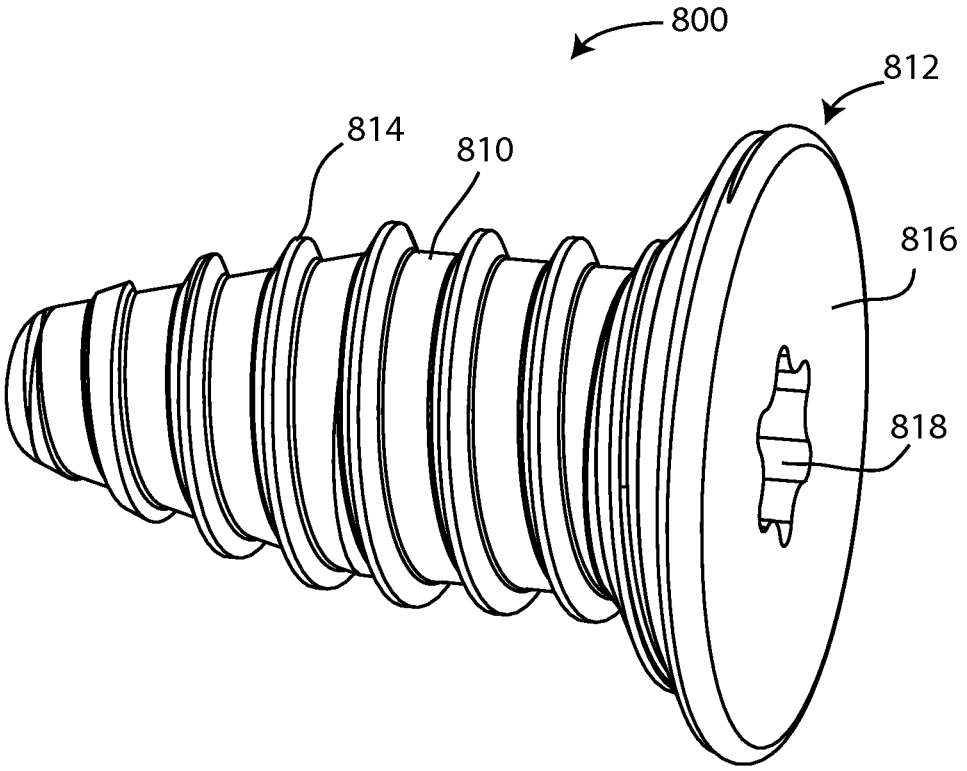


FIG. 23

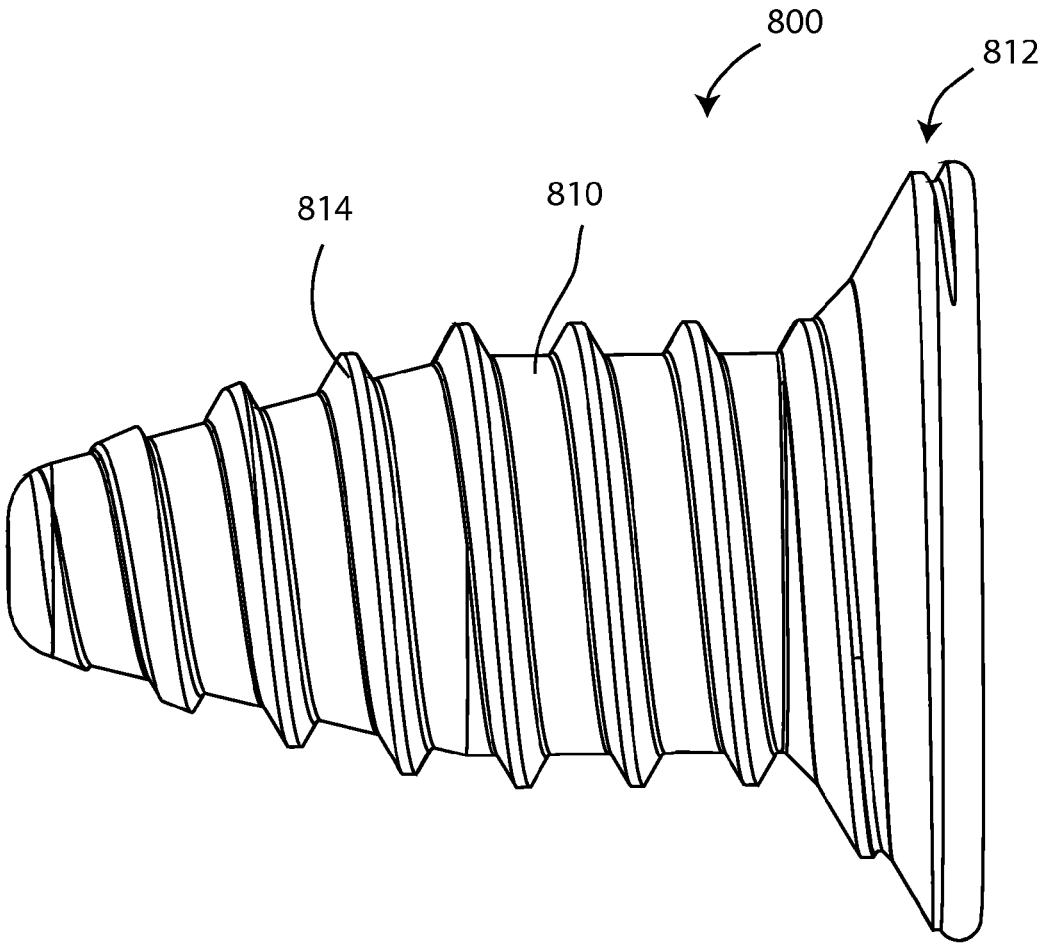


FIG. 24

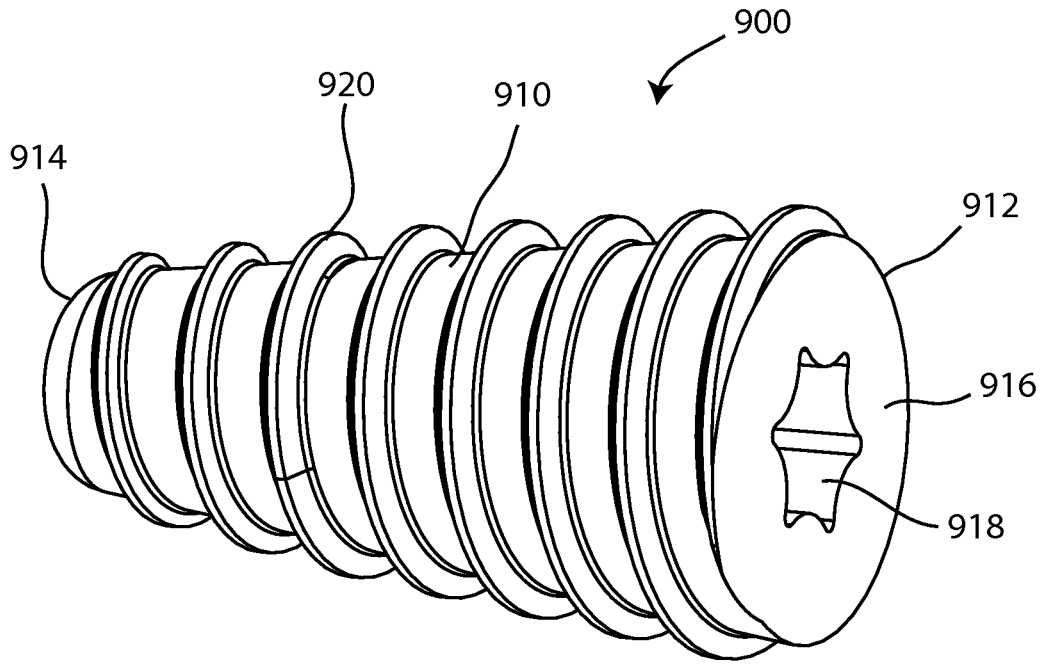


FIG. 25

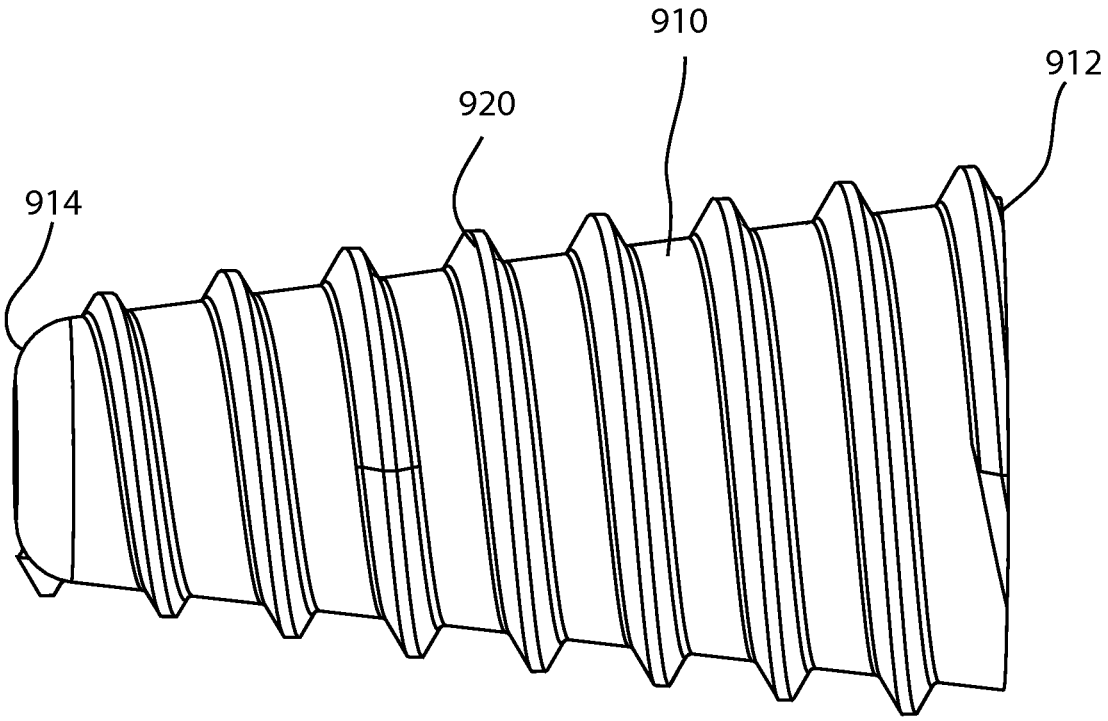


FIG. 26

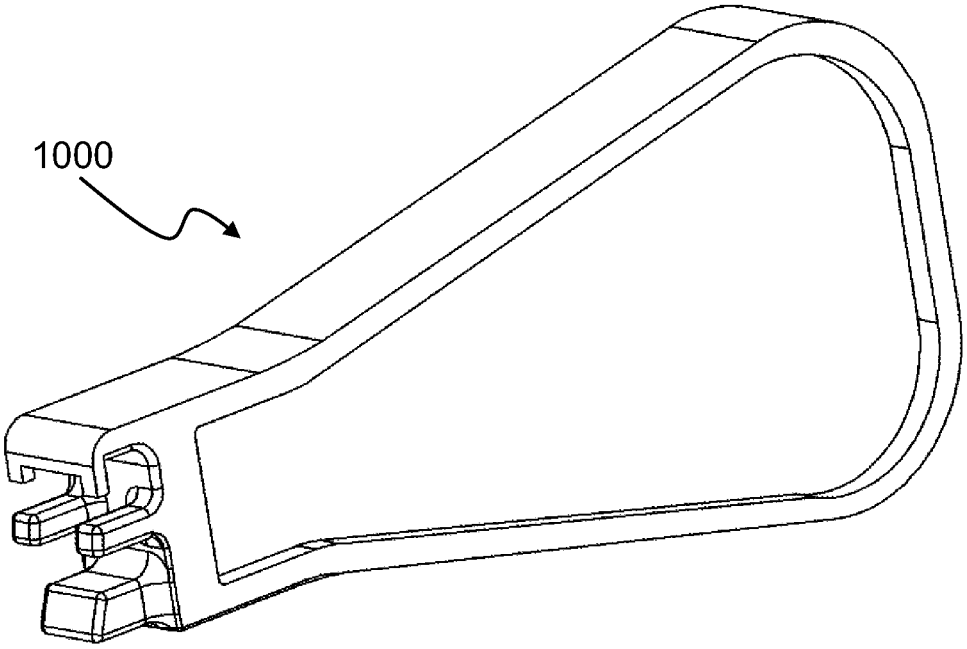


FIG. 27A

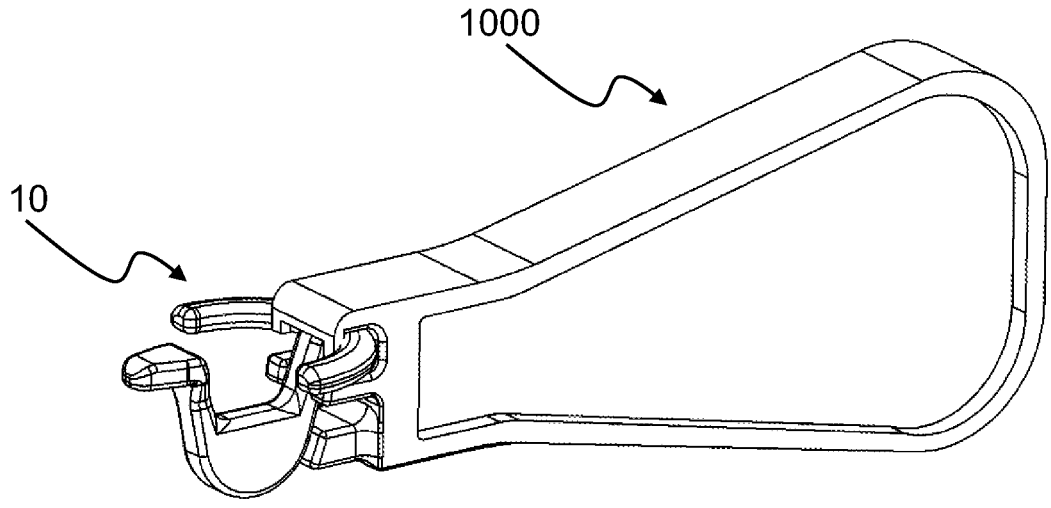


FIG. 27B

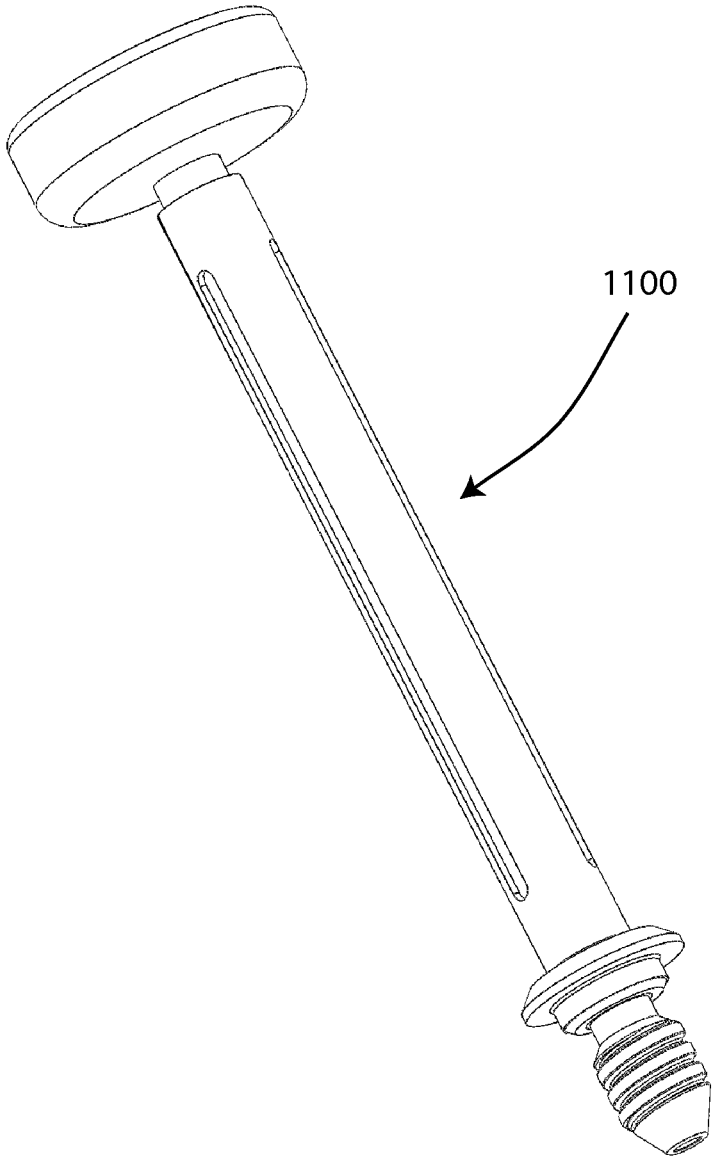


FIG. 28

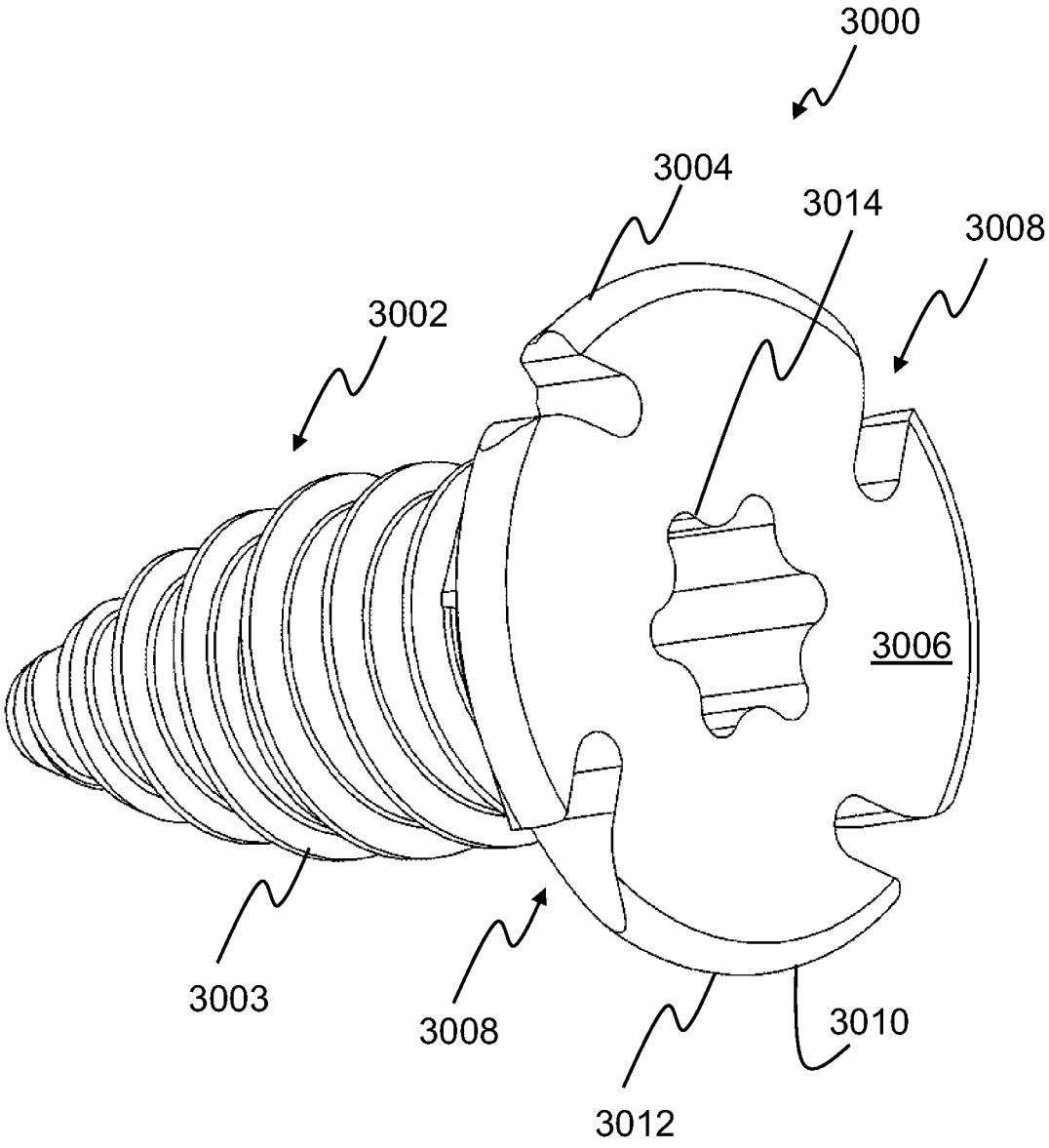


FIG. 29

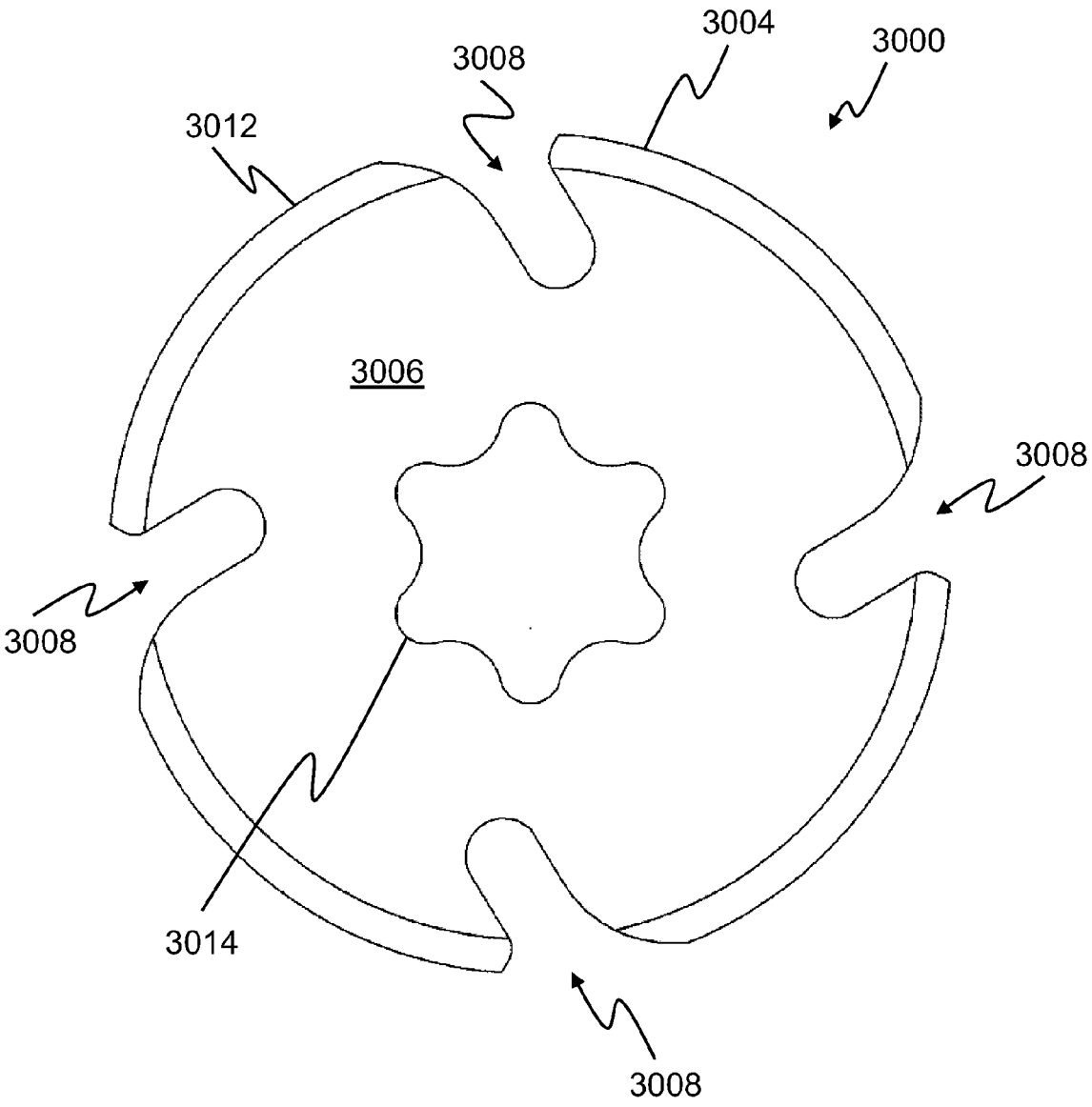


FIG. 30A

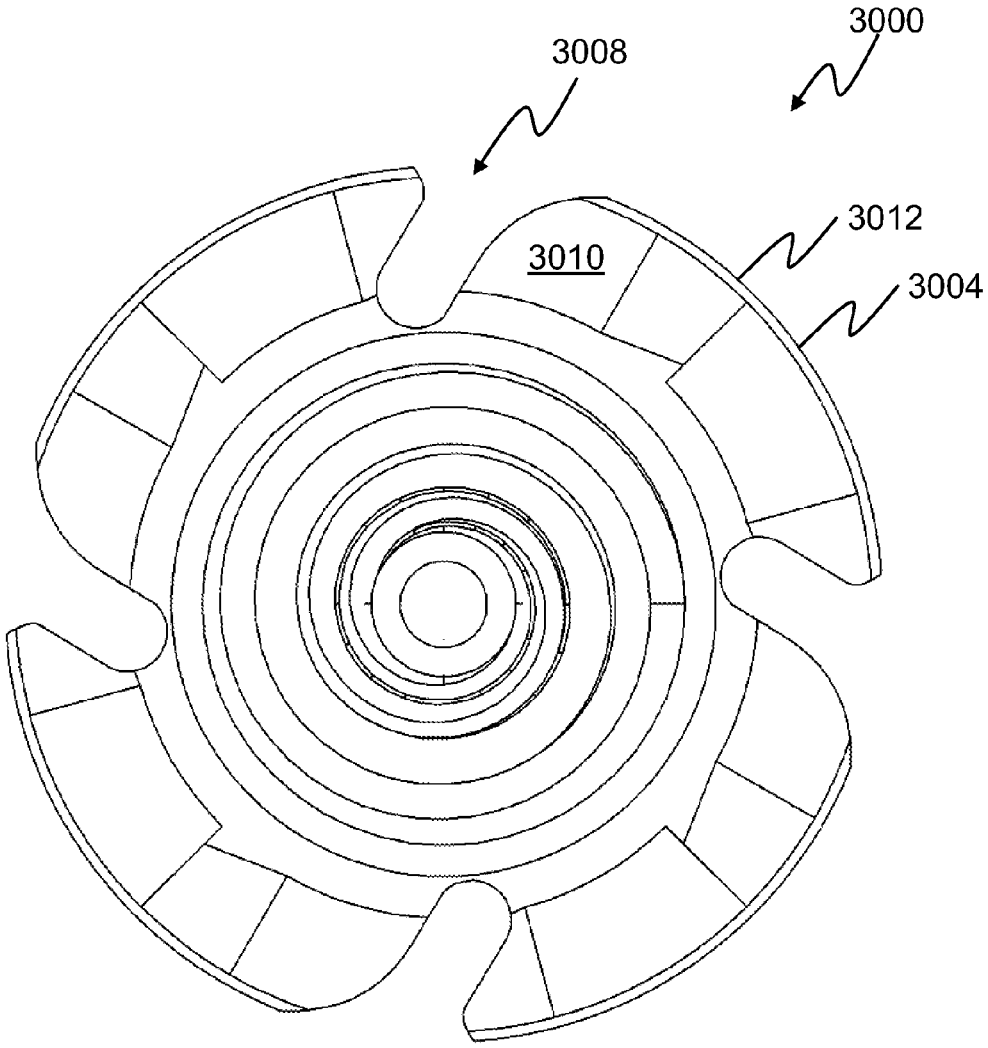


FIG. 30B

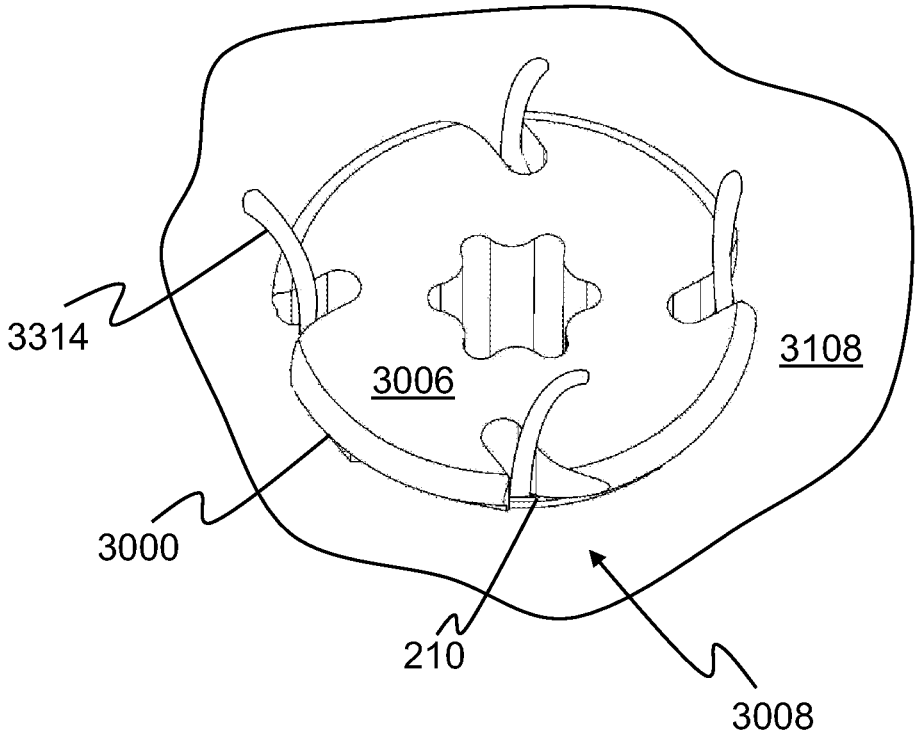


FIG. 31A

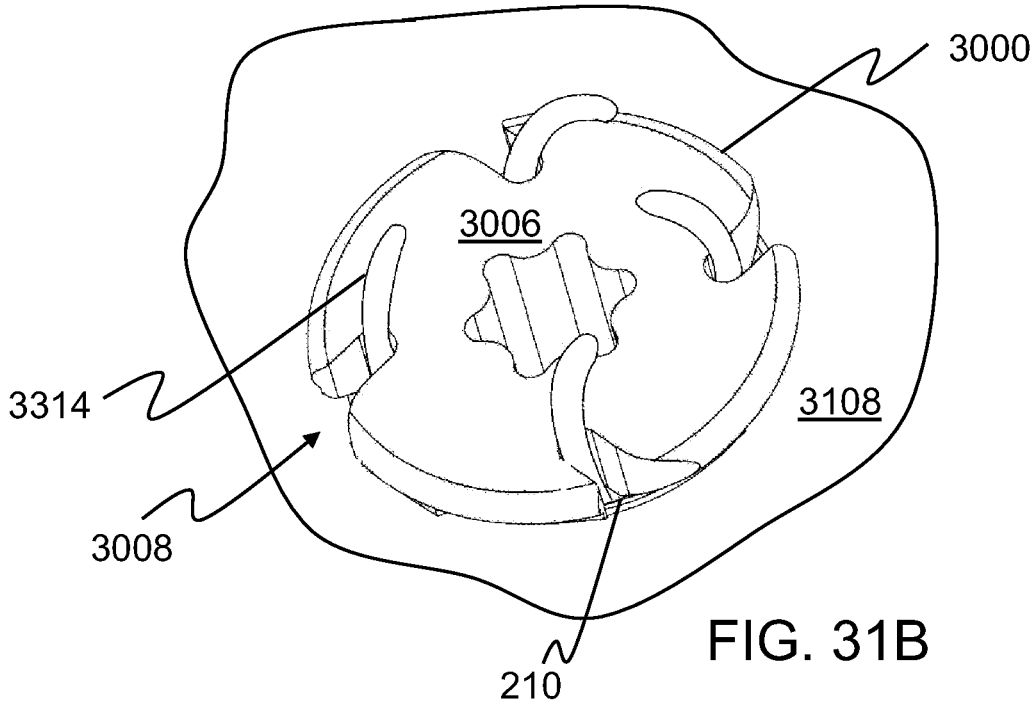


FIG. 31B

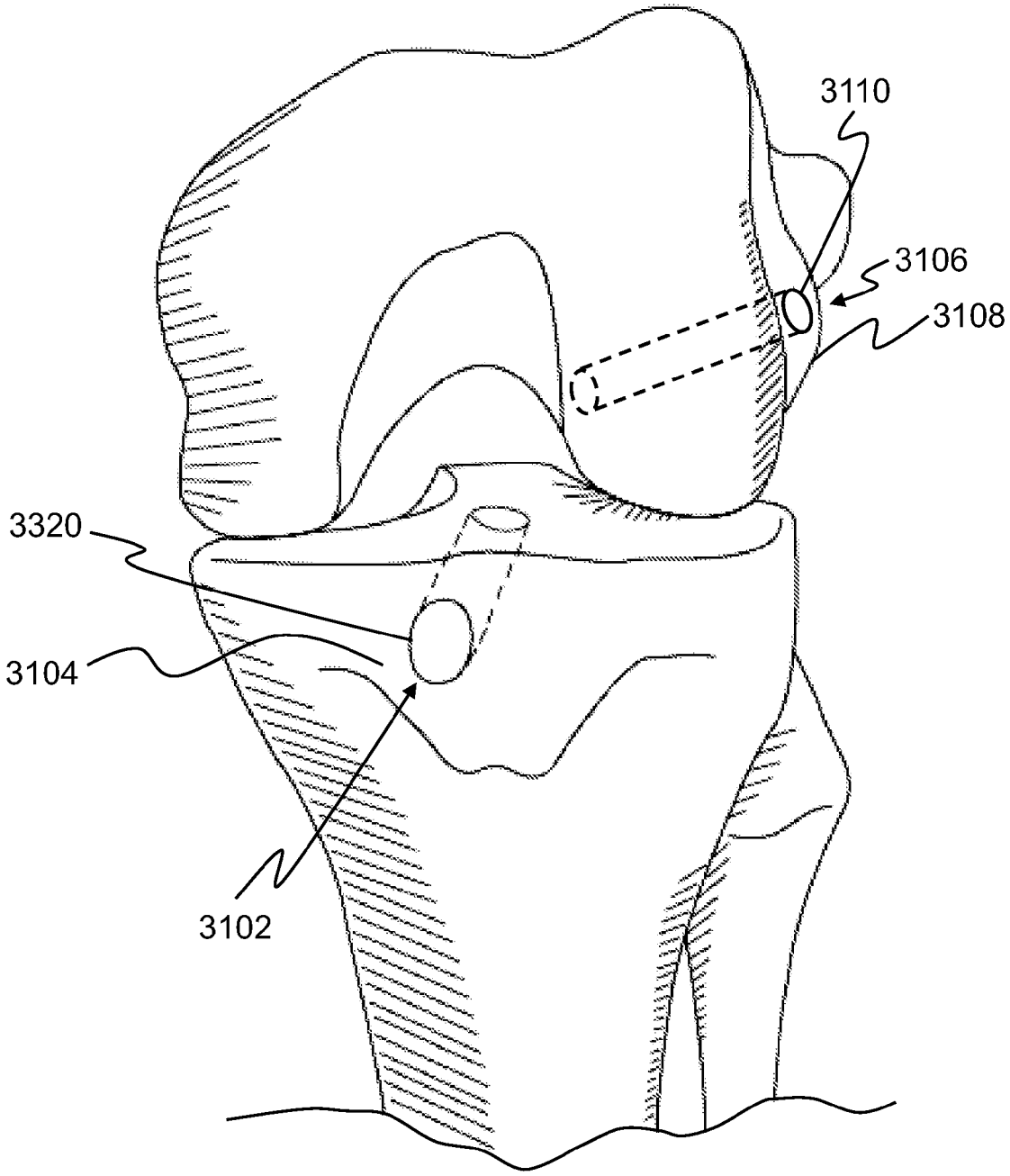


FIG. 32A

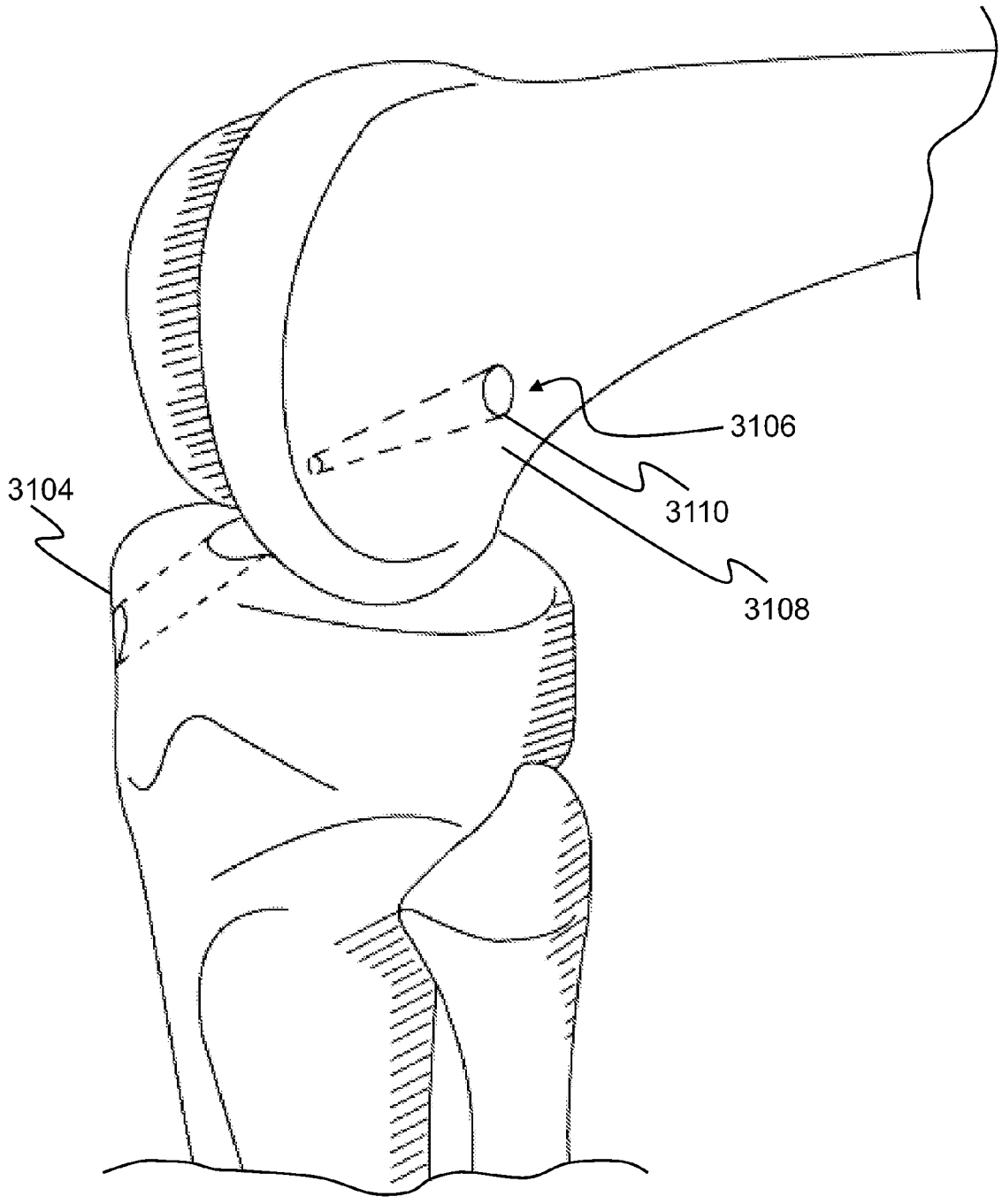


FIG. 32B

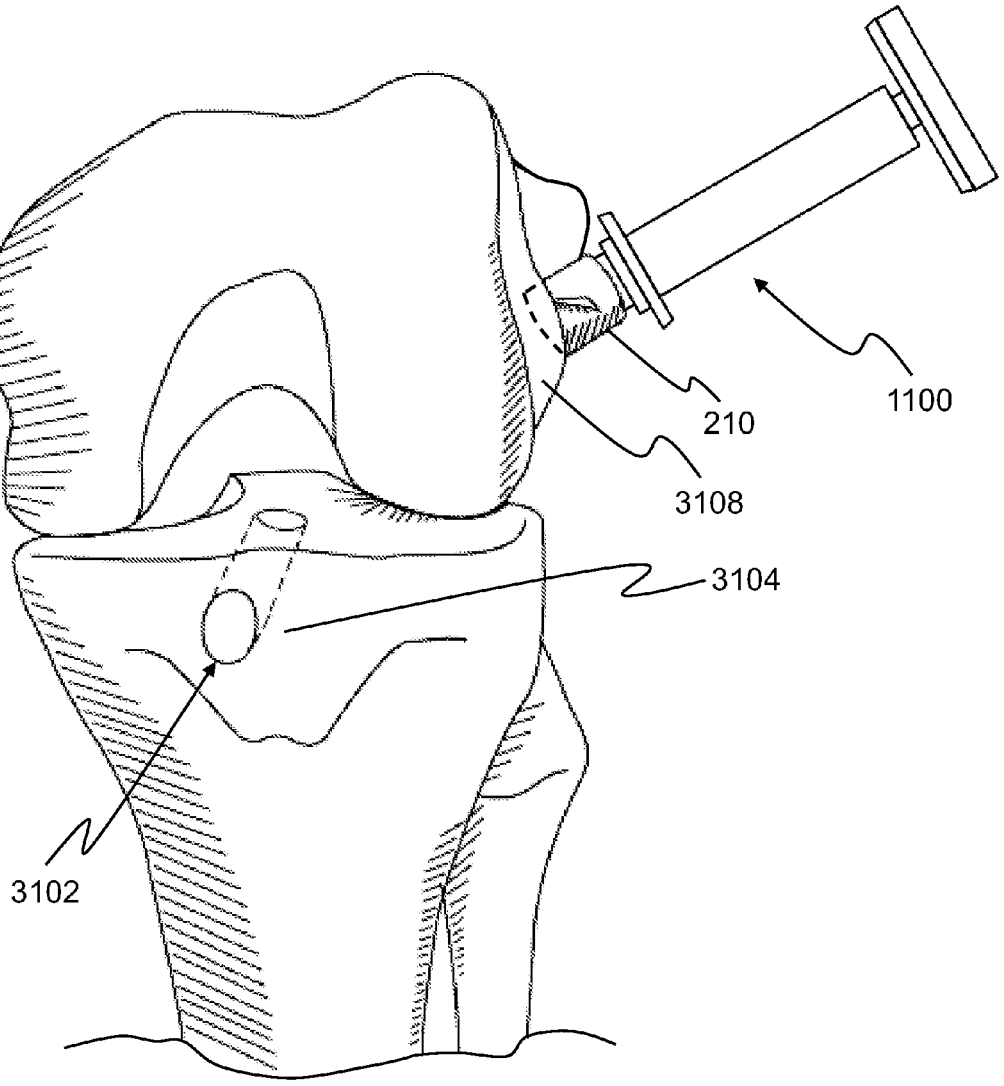


FIG. 32C

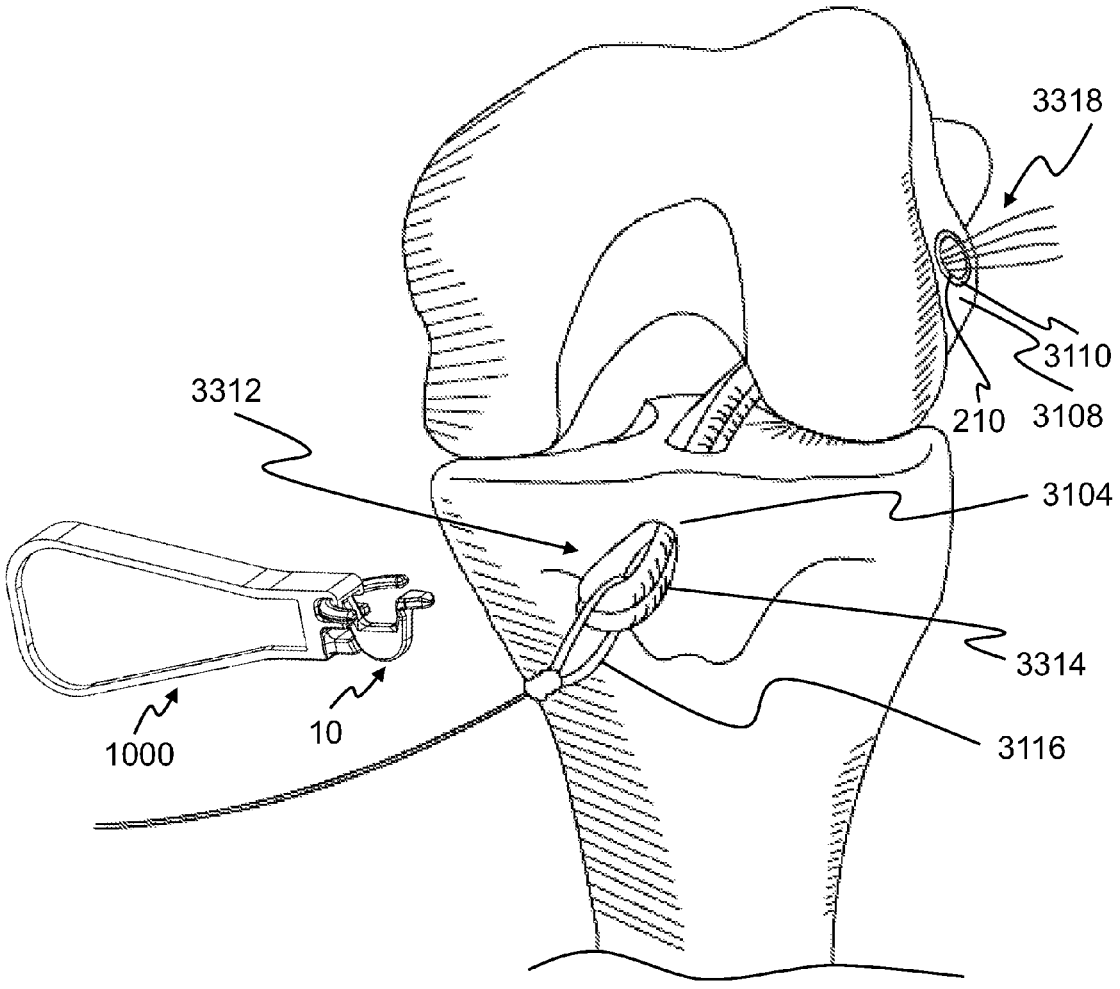


FIG. 32D

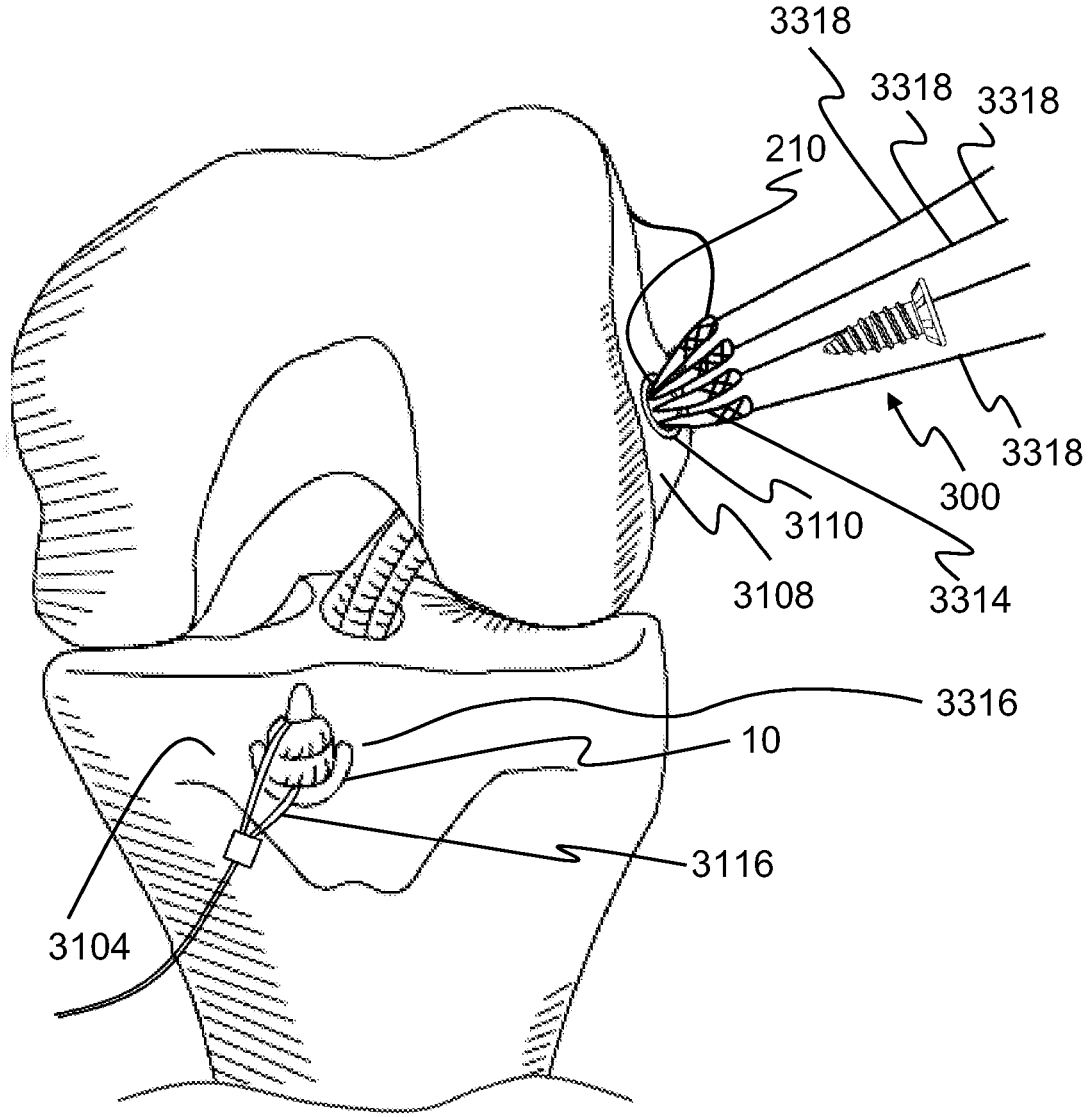


FIG. 32E

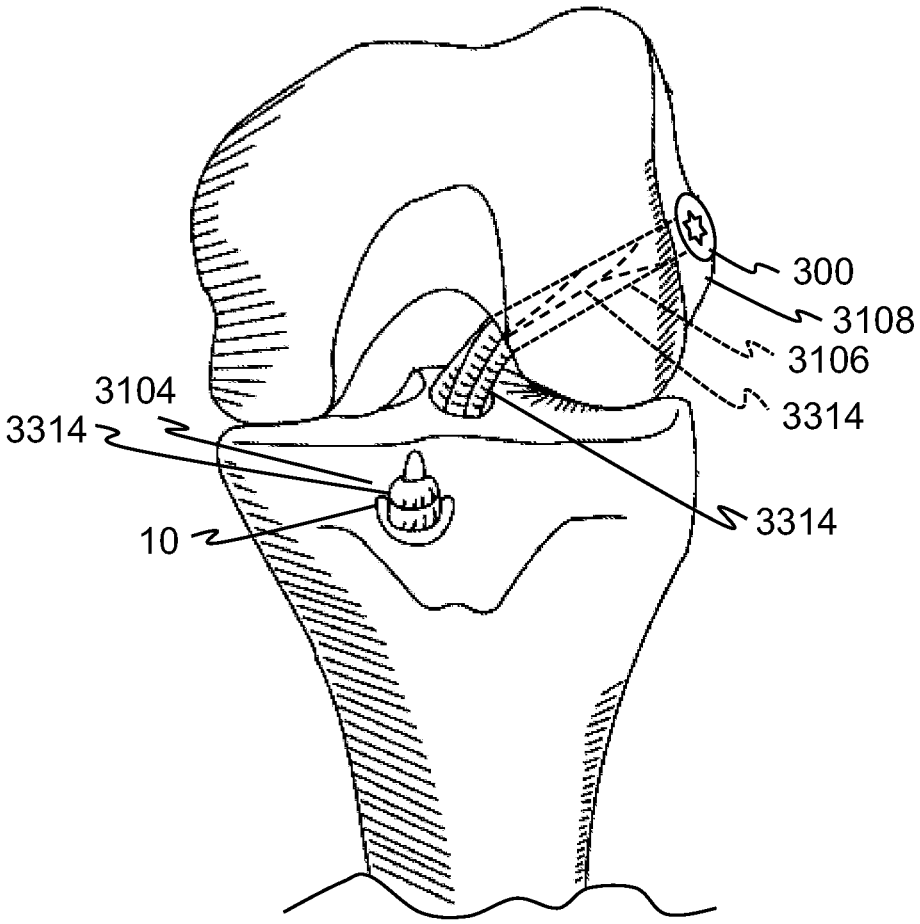


FIG. 32F

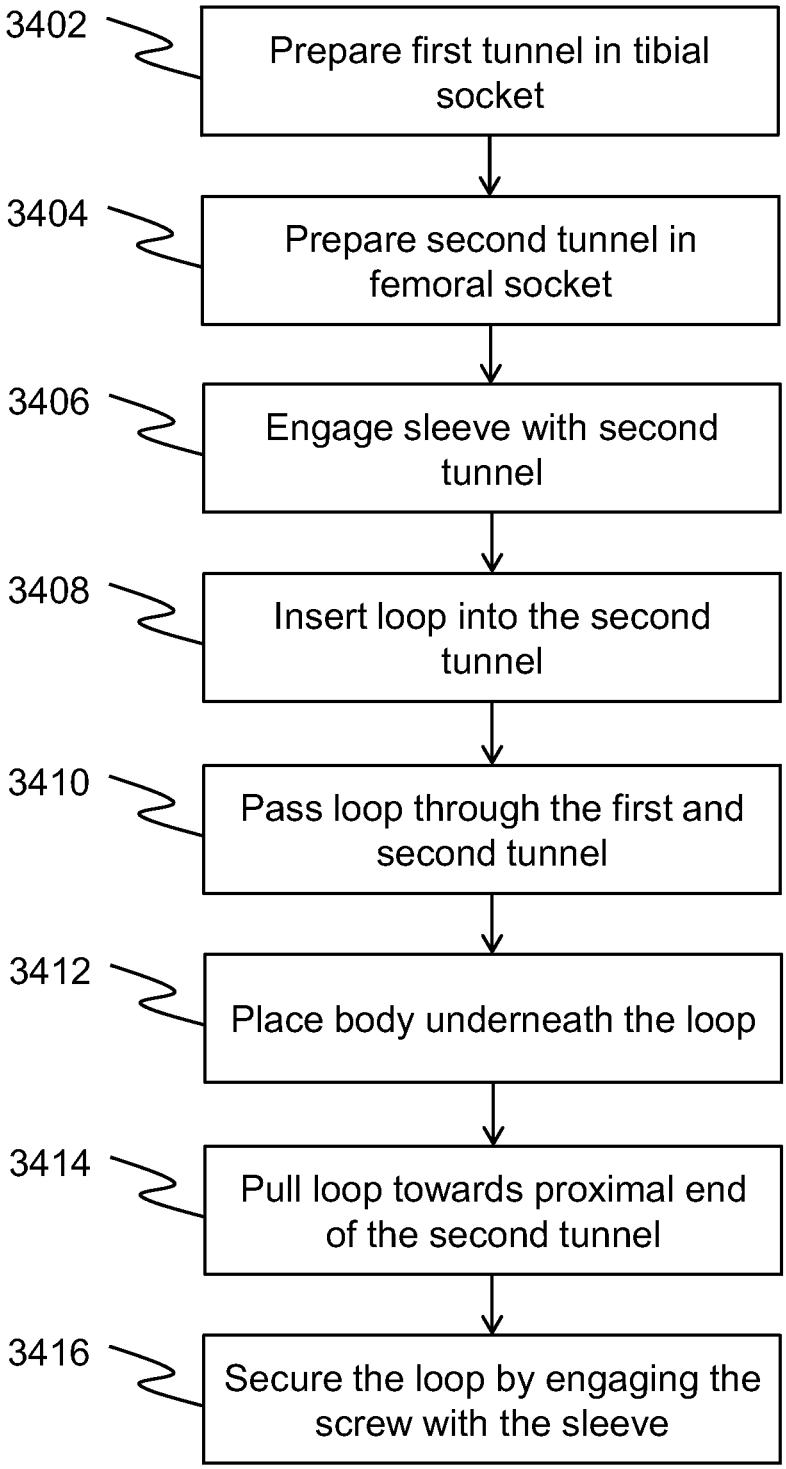
3402
Prepare first tunnel in tibial socket
3404
Prepare second tunnel in femoral socket
3406
Engage sleeve with second tunnel
3408
Insert loop into the second tunnel
3410
Pass loop through the first and second tunnel
3412
Place body underneath the loop
3414
Pull loop towards proximal end of the second tunnel
3416
Secure the loop by engaging the screw with the sleeve

FIG. 33

# GRAFT FIXATION

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of prior U.S. Provisional Patent Application No. 61/770,000 filed Feb. 27, 2013, and is entitled GRAFT FIXATION. The above-identified documents are incorporated herein by reference.

## BACKGROUND

1. Technical Field

The present disclosure relates to graft fixation including Anterior Cruciate Ligament (ACL) graft reconstruction and fixation. More specifically this disclosure relates to (1) ACL graft strand fixation within a bone tunnel and (2) extra-cortical fixation of a graft with an extra-cortical fixation loop fixation device, or button. The present disclosure also relates to methods for using the devices. It is also contemplated that the systems and methods provided herein, or any adaptations, may be useful outside of and beyond ACL graft construction and fixation and beyond any sports medicine knee repair.

2. The Relevant Technology

One attribute of ACL repair surgery is the fixation of the ACL graft through a bone tunnel providing intra-cortical and extra-cortical fixation. Adequate fixation to maintain the graft and appropriate tension is the common challenge. Therefore, there is a need to have adequate graft fixation either through intra-cortical or extra-cortical fixation as necessary for the specific patient's needs while maintaining a minimal extra-cortical profile regardless of the type of fixation, either an extra-cortical fixation loop fixation device or a bone tunnel and sleeve construct.

The implants described herein are designed to be utilized with bone tunnels that are drilled or reamed from the outside surfaces of the bone towards the central notch where the ACL resides. This methodology provides access for implantation through individual incisions through the skin.

The implants described herein are designed to work within shortened all-epiphyseal tunnels in comparison to more traditional reconstruction methods. The loop fixation construct was designed specifically with the intent to maximize graft to tunnel contact area so as to promote healing. The screw and sleeve construct was developed as a means of obtaining comparable fixation strengths within shorter tunnel lengths.

## BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention will now be discussed with reference to the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope.

FIG. **1** is a perspective view of a loop fixation device, or button, or body;

FIG. **2** is a bottom perspective view of the loop fixation device of FIG. **1**;

FIG. **3** is a top view of the loop fixation device of FIG. **1**;

FIG. **4** is a perspective view of an alternate embodiment loop fixation device, or body;

FIG. **5** is a top view of the loop fixation device of FIG. **4**;

FIG. **6** is a semi-exploded perspective view of a sleeve and a screw;

FIG. **7** is an engagement perspective view of the sleeve and the screw of FIG. **6**;



FIG. **7**A is a perspective view of a graft interfacing the screw of FIG. **6**;

FIG. **7**B is a perspective view of the graft restricting the screw from backing out;

FIG. **8** is a perspective view of the sleeve of FIG. **6**;

FIG. **9** is a side view of the sleeve of FIG. **6**;

FIG. **10** is a top view of the sleeve of FIG. **6**;

FIG. **11** is a bottom perspective view of the screw of FIG. **6**;

FIG. **12** is a top perspective view of the screw of FIG. **6**;

FIG. **13**A is a side view of the screw of FIG. **6**;

FIG. **13**B is a cross-sectional side view of the screw of FIG. **6**;

FIG. **14** is a perspective view of an alternate embodiment sleeve with a lip;

FIG. **15** is a bottom perspective view of the sleeve of FIG. **14**;

FIG. **16** is a top view of the sleeve of FIG. **14**;

FIG. **17** is a perspective view of an alternate embodiment sleeve with a plurality of keels;

FIG. **18** is a top view of the sleeve of FIG. **17**;

FIG. **19** is a perspective view of an alternate embodiment sleeve with a hex shaped body;

FIG. **20** is a top view of the sleeve of FIG. **19**;

FIG. **21** is a perspective view of an alternate embodiment screw with a larger diameter body;

FIG. **22** is a side view of the screw of FIG. **21**;

FIG. **23** is a perspective view of an alternate embodiment screw with thread extending the entire length of the body and head;

FIG. **24** is a side view of the screw of FIG. **23**;

FIG. **25** is a perspective view of an alternate embodiment headless screw;

FIG. **26** is a side view of the screw of FIG. **25**;

FIG. **27**A is a perspective view of an installation instrument for use with the loop fixation device of FIG. **1**;

FIG. **27**B is a perspective view of the installation instrument of FIG. **27**A engaging the loop fixation device of FIG. **1**;

FIG. **28** is a perspective view of an installation instrument for use with the screw and sleeve of FIGS. **7** and **8**;

FIG. **29** is a perspective view of an alternate embodiment screw with slots;

FIG. **30**A is a top view of the screw of FIG. **29**;

FIG. **30**B is a bottom view of the screw of FIG. **29**;

FIG. **31**A is a perspective view of a graft interfacing the screw of FIG. **29**;

FIG. **31**B is a perspective view of the graft restricting the screw of FIG. **29** from backing out;

FIG. **32**A is a perspective view of a first tunnel created in a tibial socket;

FIG. **32**B is a perspective view of a second tunnel created in a femoral socket;

FIG. **32**C is a perspective view of a sleeve being engaged with the femoral socket of FIG. **32**B;

FIG. **32**D is a perspective view of a graft being passed through the first and second tunnel of FIGS. **32**A and **32**B;

FIGS. **32**E and **32**F are perspective views of the body of FIG. **1** being engaged with the graft, and the screw of FIG. **11** being engaged with the sleeve; and

FIG. **33** is a flow chart of a method of ACL reconstruction.

## DETAILED DESCRIPTION

The present invention relates to ACL graft reconstruction and fixation. The following description illustrates the principles of the invention, which may be applied in various ways

to provide many different alternative embodiments. This description is not meant to limit the inventive concepts in the appended claims.

The present technology may be employed in an ACL graft retention device for ACL and other sports medicine and soft tissue repair. The present technology may provide firm graft retention from a cortical fixation device or a device for fixing a graft within a bone-tunnel. While exemplary embodiments of the present technology have been shown and described in detail below, it will be clear to the person skilled in the art that changes and modifications may be made without departing from its scope. As such, that which is set forth in the following description and accompanying drawings is offered by way of illustration only and not as a limitation. In addition, one of ordinary skill in the art will appreciate upon reading and understanding this disclosure that other variations for the technology described herein can be included within the scope of the present technology.

Referring to FIGS. **32**A-**32**E, a system may be used for ACL graft reconstruction. The system may include a body **10**, a sleeve **210** and a screw **300**. A first tunnel **3102** is prepared in a tibial socket **3104**, which may be referred to as first member. A second tunnel **3106** is prepared in a femoral socket **3108**, which may be referred to as second member. The sleeve **210** is engaged with the second tunnel **3106** at a proximal end **3110**. A loop **3312** is formed using a graft **3314**, which may be referred to as a flexible member. The loop **3312** is inserted into the second tunnel **3106**. The loop **3312** is passed through the second tunnel **3106** and the first tunnel **3102**, and is made accessible outside the first tunnel **3102**. At least a portion of the body **10** is placed underneath the loop **3312**. Subsequently, the loop **3312** is pulled towards the proximal end **3110** of the second tunnel **3106** until further movement of the graft **3314** is restricted by a portion of the body **10**, which engages with an outside surface **3316** of the tibial socket **3104**. Thereafter, the screw **300** is engaged with the sleeve **210**. The engagement of the screw **300** and the sleeve **210** results in securing of the graft **3314** at the proximal end **3110** of the second tunnel **3106** defined in the femoral socket **3108**.

Referring to FIGS. **1**-**3**, a body **10**, which may be a cortical loop fixation device, or loop fixation button, or button, includes a single piece that may perform two functions. The body **10** may include a first flange **12**. A second flange **14** may also be present, but separate from the first flange **12**. One or more such flanges may be referred to as engagement means. The first flange **12** may be substantially circular on a top portion of the body **10**. The second flange **14** may be considered a lip for a protrusion. Between the first and second flanges **12**,**14** is a retention portion **16**. The retention portion **16** may also be referred to as graft retention portion or a graft hook, or retention means. The retention portion **16** connects the first and second flanges **12**,**14**.

The first and second flanges **12**, **14** may lie in a plane that is normal to the retention portion **16**. A plane about which the retention portion **16** is at least substantially symmetrical may be perpendicular to a plane in which the first and second flanges **12**,**14** may lie.

The first flange **12** may include an engaging surface **22**. Likewise, the second flange **14** may include an engaging surface **24**. A plane in which the engaging surface **22** of the first flange **12** lies may be perpendicular to the plane about which the retention portion **16** is at least substantially symmetrical. Likewise, a plane in which the engaging surface **24** of the second flange **14** lies, may be perpendicular to a plane about which the retention portion **16** is at least substantially symmetrical.

In an embodiment, a plane in which the engaging surface of the first flange lies may be oblique to the plane about which the retention portion **16** is at least substantially symmetrical. Likewise, a plane in which the engaging surface of the second flange lies may be oblique to a plane about which the retention portion **16** is at least substantially symmetrical.

In another embodiment, a plane in which the engaging surface of the first flange lies may be oblique to the plane about which the retention portion **16** is at least substantially symmetrical. Whereas a plane in which the engaging surface of the second flange lies may be perpendicular to a plane about which the retention portion **16** is at least substantially symmetrical.

In yet another embodiment, a plane in which the engaging surface of the first flange lies, may be oblique to a plane about which the engaging surface of the second flange lies.

In an embodiment, at least one of the engaging surfaces of the flanges has a flat configuration.

In another embodiment, at least one of the engaging surfaces of the flanges has a curved configuration.

In yet another embodiment, at least one of the engaging surfaces of the flanges compliment the topography of a surface with which it interfaces.

The alignment of the first flange, the second flange and the retention portion with respect to each other is such that, engaging surfaces of each of the flanges adequately interface with corresponding cortical bone surfaces against which they may be pressed.

The flanges **12**,**14** are configured to rest on the cortical surface of a bone while the retention portion **16** is configured to rest inside a bone tunnel and engage a tissue graft. The retention portion **16** may be placed underneath the loop of a tissue graft outside of the bone tunnel. The retention portion **16** secures the tissue graft to the body **10**, and the flanges **12**,**14** of the body **10** secure the body **10** to the bone.

As stated previously, the first flange **12** may be substantially circular wherein the arms **18**,**20** of the first flange **12** extend toward the second flange **14** in a circular projection and opposite each other where the first arm **18** may extend in a counter-clockwise direction and the second arm **20** may extend in a clockwise direction. The arms **18**,**20** may terminate forming a half circle and terminating prior to extending entirely to the second flange. However, it will be appreciated that the arms **18**,**20** may extend less than forming a half circle or greater than forming a half circle and may extend almost entirely to the second flange **14**. A bone engaging surface **22** of the first flange **12** may be flat to engage the flat surface of the cortical bone.

The second flange **14** may include a large protrusion extending in a direction normal to the retention portion **16** and in a direction opposite the first flange **12**. The second flange **14** may be a constant shape as it extends from the graft hook **16** or it may taper the further it extends. A bone engaging surface **24** of the second flange **14** may be flat, similar to that of the first flange **12**, to engage the flat surface of the cortical bone. By engaging the cortical surface of the bone the flanges prevent the loop fixation device **10** from being drawn into the bone tunnel when the tissue graft is engaged and tensioned. The bone engaging surfaces **22**, **24** may be textured, roughened, coated, or otherwise structured to positively engage bone in the short and/or long term.

The retention portion **16** may be V, U or J shaped to engage a tissue graft. A first leg **26** comprises one side of the U and a second leg **28** comprises the other side of the U with a retention portion or central portion **30**, or graft interfacing portion, connecting the two legs **26**,**28**. The central portion **30** may be rounded for a U or J shape or pointed for a V shape. The first

leg **26** extends from the central portion **30** to the first flange **12**, and the second leg **28** extends from the central portion **30** to the second flange **14**. The central portion **30** may include a flat surface on the base of a first, inside, wall **32** or it may have a continuing rate of curvature with no flat surface.

The first and second legs may have the same length. Alternatively, the first and second legs may have the varying lengths.

The retention portion **16** includes a first, inside, wall **32** and a second, outside, wall **34**. The transition from the central portion **30** to the legs, **26**,**28** may be abrupt forming hard angles on the inside wall **32** or it may be gradual with a continuing rate of curvature. However, it will be appreciated that the inside wall **32** may include hard angles in place of the smooth U or hook shaped transitions and may take a partial polygon shape as well. The outside wall **34** may match the curvature of the inside wall **32** and thus may form a substantially U-shape with a gradual smooth transition from one leg **26**, **28** through the central portion **30** to the other leg **26**,**28**. Although, fixed angles rather than a circular transition may also be considered for the outside wall **34** with a polygonal shape. The outside wall **34** is not required to match the curvature or shape of the inside wall **32**.

The legs **26**,**28** of the graft hook **16** may extend non-parallel upward toward the flanges **12**,**14**. In another embodiment the legs **26**, **28** may extend parallel toward the flanges.

In an embodiment, surfaces of the legs **26**,**28** facing the graft may be parallel to each other, while surfaces of each of the legs **26**,**28**, which are at least to some extent opposite to the surface of the legs **26**,**28** facing the graft, may be oblique to each other.

In an embodiment, one or more slots (or other resilient material or structure) may be defined in at least one of the legs **26**, **28** and/or the central portion **30**, such that, when force is applied on the legs **26**,**28** by wall of the tunnel when the body **10** is pulled into the tunnel, the legs **26**, **28** are moved closer to each other, thereby defining an interference fit between the wall of the tunnel and the legs **26**,**28**.

The central portion **30** of the retention portion **16** may have a larger side view footprint for engaging the tissue graft. The central portion **30** may comprise more material relative to the arms of the graft hook **16**.

Referring to FIG. **3** it is shown that a top view of the loop fixation device may resemble an anchor.

Referring to FIGS. **4** and **5**, an alternate embodiment of a body, which may be a cortical loop fixation device **110** or system, includes a first flange **112** and a second flange **114**, or first and second flange hooks because of their curved feature. The first and second flanges **112**, **114** may extend in a circular fashion toward an opposite end of the loop fixation device **110** and in either a clockwise or counter-clockwise direction. The flanges **112**,**114** in this embodiment are extending in a counter clockwise direction and not intersecting; however, it will be appreciated that the flanges **112**,**114** may extend greater than or less than a quarter turn.

The loop fixation device **110** also includes a graft retention portion **116**, or graft hook, which may be substantially similar to the previous embodiment with a central portion **130**, or graft interfacing portion, or saddle, a first leg **126** and a second leg **128**. The saddle **130** engages and maintains the graft. Similar to the previous embodiment, the flanges **112**, **114** may include bone engaging surfaces **122**, **124** on each of bottom surfaces of the flanges to engage the cortex of the bone. By engaging the cortex, the flanges **112**,**114** prevent the loop fixation device **110** from being drawn into the bone tunnel when the graft is engaged and tensioned.

Advantages to either embodiment of the loop fixation devices, **10**, **110** is that neither loop fixation device may require toggling of the loop fixation device to appropriately position the loop fixation device. Another distinct advantage of these loop fixation devices **10**,**110** is no need for a flexible medium such as a suture or cord between the graft and the loop fixation device **10**,**110**. Therefore, this technology contributes to increased stiffness of the entire graft reconstruction. Furthermore the loop fixation device **10**,**110** is positioned and engages the tissue graft outside of the bone tunnel and does not need to be passed through the bone tunnel. The loop fixation device **10**,**110** has less likelihood of falling inside the bone tunnel because of its shape and dimensions and is especially useful in instances and applications where surgeons ream the bone tunnel from the outside cortical bone toward the inside, intercondylar notch where the cortical wall around the proximal portion of the tunnel (the outside cortical portion) of the tunnel is no longer intact.

Referring to FIGS. **27**A and **27**B, an installation instrument **1000** may be used to aid in the installation of the body **10** in connection with the graft **3314**.

A separate structure may be utilized to provide alternate graft fixation through the use of a sleeve and screw and will be described further herein. Referring to FIGS. **6**, **7**, **7**A and **7**B, a graft retention device **200** may include a sleeve **210** and a screw **300**. The screw **300** may be inserted into the sleeve **210** after at least a portion of a tissue graft has passed through the sleeve **210**. The screw **300** provides interference fixation of the tissue graft by radial force onto the tissue graft toward an inner wall of the sleeve **210** with the screw **300** as the screw is advanced further into the sleeve **210**. FIG. **6** illustrates the screw **300** partially engaged within the sleeve **210** while FIG. **7** illustrates the screw **300** fully engaged within the sleeve **210**.

Referring to FIGS. **6**-**10**, the sleeve **210**, which may be referred to as accommodation means, may be a cylinder, or tubular, with an inside wall **212** and an outside wall **214** with a bore **216**, or tunnel, which may be a central bore and may be defined by a central axis, passing at least partially through the center thereof and may pass entirely, and longitudinally, through the sleeve **210**. The inside wall **212** may include female threads for engaging a screw. It should be understood that the threads on the inside wall **212** may be replaced with ridges, a tooth or teeth or barbs or any other tractive features or means to allow the sleeve **210** to grab and capture the graft. The bore **216** may maintain a constant diameter through the entire sleeve **210** or the diameter may become smaller toward a distal end. The outside wall **214** may include radial fins **218** projecting from the outside wall **214**. The fins **218** may provide anti-rotation of the sleeve **210** during installation of the screw **300** within the sleeve **210**. In this situation, the fins **218** may twist counter-clockwise to resist screw insertion torque. The fins **218** may include a helical turn and have a larger cross-sectional footprint toward the proximal end of the sleeve **210**. As the fins **218** advance toward the distal end, the fins **218** may taper to a point and eventually become flush with the outside wall **214** of the sleeve **210**. The proximal end of the fins **218** may not reach the proximal end of the sleeve **218**. The fins **218** may have a flat proximal surface **220** that is normal to the outside wall **214** of the sleeve and which may prevent withdrawal of the sleeve from out of a bone tunnel by providing an anti-back out feature.

The outside wall **214** may have a constant circumference from the proximal end to the distal end. Although, referring to FIG. **9**, a taper **222** may extend from the distal end of the sleeve **210** wherein the circumference is relatively smaller than the main body of the sleeve **210**. The fins **218** may extend

into the taper **222** and become flush with the taper **222**, the fins terminating at the taper **222**. The taper **222** may provide a lead-in to aid in the introduction of the sleeve into the bone tunnel.

The sleeve **210** may contain the hoop stress of the screw impinging onto the graft. This may prove advantageous where the forces may become disruptive of nearby growth plates of growing children. The sleeve **210** provides more consistent clamping of the graft by providing stability and keeping the screw **300** from tracking off axis and outside the bounds of the bone tunnel while also providing a controlled exterior interface with the bone tunnel.

There may be a clearance between the inner wall **212** of the sleeve **210** and the screw **300** to allow for the tissue graft to pass through the sleeve and still allow the screw **300** to engage or be coupled to the sleeve **210**. Referring to FIGS. **11-13**B, the screw **300** includes a body **310** and a head **312**. The body **310** may include threads **314**, which may be male threads configured to engage the female threads of the inner wall **212** of the sleeve **210**. The threads **314** of the screw **300** and the threads of the sleeve **210** may provide further traction to prevent slippage of the tissue graft along the tunnel sleeve axis. The body **310** may taper extending away from the head **312** toward a distal end allowing for easier insertion into the sleeve **210** when the tissue graft is within the sleeve **210**.

A portion of the body **310** which engages the sleeve **210** may have a uniform cross-sectional diameter, whereas a portion of the body **310**, which extends beyond the distal end of the sleeve **210** may taper towards the distal end of the screw **300**.

The head **312** may include a flat proximal surface **316** with a central void **318**, the central void **318** extending at least partially inward from the flat proximal surface toward a distal end to allow access for a surgical tool. The central void **318** may be star shaped, polygonal or any other shape to allow access of and engaging of a tool for insertion of the screw **300** into the sleeve **210** and the central void **318** may be entirely enclosed. The head **312** may have a larger diameter than the body **310** of the screw **300** wherein the diameter decreases from the head to the body creating a shoulder or lip such that the head **312** may rest against the cortex of the bone on the edge of the bone tunnel which may provide resistance to axial translation of the device **200**. The head **312** may also include barbs **320**, a tooth or teeth, positioned where the diameter is decreasing from the head **312** to the body which may also be the point where the tissue graft and the bone interface. The barbs **320** are configured in a direction to prevent the screw **300** from backing out.

Referring to FIGS. **7**A and **7**B, the screw **300** is engaged with the sleeve **210** after one (or more) strands of the graft **3314** is (or are) projected out of the sleeve. Strands of the graft **3314** are pressed between the sleeve body **310** and inside wall **212** of the sleeve **210**. Additionally, at least a portion of the graft **3314** may be projecting out of the sleeve **210** and may be exposed to an outside surface of the femur **3108**. In the event of the screw **300** rotating in a direction opposite to a direction in which it is turned for engagement with the sleeve, an interface created between one or more barbs **320** and the strand of the graft **3314** prevents or otherwise inhibits it from rotating in the opposite direction, thereby resulting in an anti-back-out feature of the screw **300**.

Referring to FIG. **13**B, the screw **300** may further be cannulated with a cannula **322** passing from the central void **318** to the distal end of the screw **300**. The cannula **322** may allow passage of a guide wire or other means to direct the screw **300** to its appropriate position.

Referring to FIGS. **14-16**, an alternate embodiment of a sleeve **410** is illustrated. The sleeve **410** similarly includes an inside wall **412**, an outside wall **414** and bore **416**, or tunnel, passing through a center of the sleeve **410**. The sleeve **410** may also include a lip **420**, or flange, on the proximal end projecting from and normal to the outside wall **414**. The inside wall **412** may be threaded, with female threads, to receive a male threaded screw, which may be similar to the screw **300** previously described. However, other screws such as those depicted and described in FIGS. **21-26** may also be used. But more specifically this sleeve **410** may be more conducive to accepting a screw as depicted and described in FIGS. **25** and **26**. The lip **420** may comprise a flat bottom surface **422** to engage the cortical bone to prevent the sleeve **410** from retracting entirely into the bone tunnel.

Referring to FIG. **15**, the sleeve **410** may also include an anti-rotation, and anti-back out, features **418**, or fins, or keels, extending both from the outside wall **414** and the bottom surface **422** of the lip **420**. The fins may have a larger cross-sectional footprint toward the proximal end of the sleeve and may taper as the fins **418** extend toward a distal end until becoming flush with the outer wall **414** of the sleeve. The fins **418** may be radially positioned on opposite ends of the sleeve **410** or may be positioned in other configurations that space the fins **418** equidistant from each other; however, the fins may be staggered at odd angles. The number and spacing of the fins **418** can vary. The fins **418** may extend straight, without curving, from the bottom surface **422** of the lip **420** toward the distal end, with the fins **418** terminating and becoming flush with the outer wall **414** prior to the distal end.

This alternate embodiment sleeve **410** may include other features similar to the previous embodiment. For example, a taper **424** may extend from the distal end of the sleeve **410** wherein the circumference is relatively smaller than the main body of the sleeve **410**. The fins **418** may extend into the taper **424** and become flush with the taper **424**, the fins terminating at the taper **424**.

Referring to FIG. **16**, the lip **420** may include radial bulges **426** to create a larger footprint for the sleeve **410** to engage the cortical bone. The bulges **426** may be radially opposed and evenly spaced; however, the number of bulges and spacing of each may vary.

Referring to FIGS. **17** and **18**, an alternate embodiment of a sleeve is illustrated. The sleeve **510**, similar to previous embodiments, includes an inner wall **512**, an outer wall **514** and a bore **516**, or tunnel, longitudinally passing through the center of the sleeve. The inner wall **512** may include threads, female threads, for engaging male threads from a screw which may be similar to screw **300**, as previously described or those screws depicted and described in FIGS. **21-26** herein. But more specifically this sleeve **510** may be more conducive to accepting a screw as depicted and described in FIGS. **21** and **22**.

The structure of the outer wall **514** and inner wall **512** with a tapered end **522** may be substantially similar to that of the previous sleeve **210** embodiment. However, the anti-rotation features **518**, or fins, or keels, differ from the previous embodiment in that the fins **518** extend from the proximal end of the sleeve **510** wherein a flat surface **520** of the fins **518** is flush with the proximal end of the sleeve **510**. The fins **518** extend toward a distal end tapering and terminating prior to the distal end and essentially becoming flush with the outer wall **514**. The fins **518** are radially spaced along the outer wall **514** equidistant from one another. The number of fins, spacing and positioning may vary.

Referring to FIGS. **19** and **20**, an alternate embodiment of a sleeve is illustrated. The sleeve **610** may be hexagonal in

cross-sectional shape; however, any polygonal shape may also be used. Similar to the previous sleeve embodiments the sleeve **610** includes an inner wall **612**, an outer wall **614** and a bore **616**, or tunnel, longitudinally extending through the body of the sleeve **610**. The shape of the sleeve provides an engaging fit within a bone tunnel as the hard angles of the hexagonal shape prevent rotation of the sleeve when a screw engages the sleeve **610**. The inner wall **612** may include threads, female threads, for engaging male threads from a screw which may be similar to screw **300**, as previously described or those screws depicted and described in FIGS. **21-26** herein.

Each of the sleeve embodiments may contain features from any of the other sleeve embodiments. Alternate features have been contemplated such as the threads on the inside walls of each sleeve may be replaced with ridges, a tooth or teeth or barbs or any other tractive features or means to allow the sleeve **210** to grab and capture the graft. Likewise each of the bores, passageways, central axis tunnels may have a constant diameter or taper from a proximal to a distal end or vice versa.

Referring to FIGS. **21** and **22**, an alternate embodiment screw is illustrated. Screw **700** may be substantially similar to screw **300** provided that the diameter of a body **710** of screw **700** is larger than the diameter of body **310** of screw **300**. Furthermore the transition from a head **712** of screw **700** to the body **710** may be less abrupt because of the larger diameter of the body **710** as compared to the transition from the head **312** of screw **300** to the body **310**. The screw **700** includes threads **714** extending the length of the body.

The head **712** may include a flat proximal surface **716** with a central void **718**, the central void **718** extending at least partially inward from the flat proximal surface **716** toward a distal end to allow access for a surgical tool. The central void **718** may be star shaped, polygonal or any other shape to allow access of and engaging of a tool for insertion of the screw **700** into the sleeve **510**. However it will be appreciated that screw **700** may engage any of the previous depicted or described sleeves herein. The head **712** may have a larger diameter than the body **710** of the screw **700** wherein the diameter decreases from the head to the body creating a shoulder or lip such that the head **712** may rest against the cortex of the bone on the edge of the bone tunnel which may provide resistance to axial translation. The head **712** may also include barbs **720**, or tooth or teeth positioned where the diameter is decreasing from the head **712** to the body which may also be the point where the tissue graft and the bone interface. The barbs **720** are configured in a direction to prevent the screw **700** from backing out. The screw **700** may further be cannulated in a manner similar to and described regarding the screw **300** in FIGS. **11-13**B.

Referring to FIGS. **23** and **24**, an alternate embodiment of a screw is illustrated. A screw **800** comprises a body **810** and a head with threads **814** extending from the proximal end of the head **812** to the distal end of the body **810**. The head **812** may have a larger diameter than the body **810** and may taper from the distal end of the head **812** to the proximal end of the body **810**. This embodiment may include features similar to previous screws in that the screw **800** may comprise a flat proximal surface **816** with a central void **818**, the central void **818** extending at least partially inward from the flat proximal surface **816** toward a distal end to allow access for a surgical tool. The screw **800** may also be cannulated as similarly described with regard to previous screw embodiments. The central void **818** may be star shaped, polygonal or any other shape to allow access of and engaging of a tool for insertion of the screw **800** into the sleeve **410**. Screw **800** and sleeve **410** may be ideally matched for each of the devices distinct configurations; however it will be appreciated that screw **800** may engage any of the previous depicted or described sleeves herein.

Referring to FIGS. **25** and **26**, an alternate embodiment of a screw is illustrated. A screw **900** comprises a body **910** tapering from a proximal end **912** to a distal end **914** and maybe conical in shape and may have no distinct "head" of the screw **900**. The screw **900** includes threads **920** extending form the proximal end **912** to the distal end **914**. The proximal end **912** may comprise a flat proximal surface **916** with a central void **918**, the central void **918** extending at least partially inward from the flat proximal surface **816** toward a distal end **914** to allow access for a surgical tool. The screw **900** may also be cannulated as similarly described with regard to previous screw embodiments.

Referring to FIGS. **29**, **30**A and **30**B, an alternate embodiment of a screw is illustrated. A screw **3000** includes a body **3002** and a head **3004**. The body **3002** may include threads **3003**, which may be male threads configured to engage the female threads of the inner wall of the sleeve. The head **3004** may include a flat proximal surface **3006** with a central void **3014**, the central void **3014** extending at least partially inward from the flat proximal surface **3006** toward a distal end to allow access for a surgical tool. The head **3004** may define multiple slots **3008**. Alternatively, as single slot **3008** may be defined by the head **3004**. The slots **3008** extend between the flat proximal surface **3006** and a distal surface **3010** of the head **3004**. The distal surface **3010** may be a surface facing the sleeve. Further, the slots **3008** extend inward from a peripheral edge **3012** of the head **3004** towards the center of the head **3004**.

The slots **3008** may be aligned and extend radially inward from the outer circumference of the head **3004** towards the central void **3014**, at least to some extent, in the same direction as the direction in which the screw **3008** is rotated for engagement with the sleeve. The slot **3008** may define a U, V or J shaped configuration.

Referring to FIGS. **31**A and **31**B, the slots **3008** may be aligned such that strands **3314** of the graft projecting out of the sleeve **210**, and exposed to the outside surface of the femoral socket **3108**, are deflected away from the center of the head **3004**, thereby preventing the strand **3314** from being caught in the slots **3008**, when the screw **3000** is being engaged with the sleeve **210**. On the other hand, if the screw **3000** attempts to rotate in the opposite direction, the strands **3314** of the graft may be caught in the slots **3008**, thereby preventing the screw **3000** from backing out. FIG. **31**A illustrates the strands of the graft **3314** being deflected away from being caught in the slots **3008**, when the screw **3000** is rotated in an engagement direction, for engaging the screw **3000** with the sleeve **210**. FIG. **31**B illustrates the strands **3314** of the graft being caught in the slots **3008**, when the screw **3000** is rotated in a direction which is opposite to the engagement direction, thereby preventing the screw **3000** from backing out. Even if the strands **3314** of the graft were to be trimmed to prevent the strands **3314** from projecting above the proximal surface **3006** of the screw **3000**, the interface between the remaining portions of the strands **3314** located within at least a portion of one or more of the slots **3008** may still prevent the screw **3000** from backing out.

Referring to FIGS. **32**A-**33**, application of the system to ACL graft reconstruction is discussed. A first tunnel **3102** is prepared in a tibial socket **3104** (step **3402**), which may be referred to as a first member. A second tunnel **3106** is prepared in a femoral socket **3108** (step **3404**), which may be referred to as second member. The second tunnel **3106** is reamed at a proximal end **3110** for receiving the sleeve **210** and the screw

300. It shall be noted that, if the screw 300 is intended to be engaged with the wall of the second tunnel 3106, apart from being engaged with the sleeve 210, then threads may be created on the wall of the second tunnel 3106. The treads on the wall of the second tunnel 3106 may be created while reaming the second tunnel 3106.

The sleeve 210 is engaged with the second tunnel 3106 at the proximal end 3106 of the second tunnel 3106 (step 3406). The sleeve 210 may be engaged using an insertion tool 1100 illustrated in FIG. 28. The insertion tool 110 may define threads at one end, which may correspond to the threads of the sleeve 210. The sleeve 210 is engaged with the insertion tool 1100 at the threaded portion of the insertion tool 1100. Thereafter, the sleeve 210 along with the insertion tool 1100 is aligned along the axis of the second tunnel 3106. The distal end of the sleeve 210 is aligned with the proximal end 3110 of second tunnel 3106. Subsequently, force, such as by hammering, driving, screwing, twisting, or otherwise advancing, is applied over the head of the tool 1100, thereby pushing and/or rotating the sleeve 210 into the second tunnel 3106. As the sleeve 210 is pushed into the second tunnel 3106, the fins provided in the sleeve 210 cut through the wall of the second tunnel 3106. The sleeve 210 is firmly held in the second tunnel 3106 due to a friction fit, between the surface of the sleeve 210 and the wall of the second tunnel 3106, and between fins of the sleeve 210 and the bone. The fins also prevent the sleeve 210 from rotating when the screw 300 is engaged with the sleeve 210.

Further, a loop 3312 formed using a graft 3314 is inserted into the proximal end 3110 of the second tunnel 3106. A suture 3116 may be engaged at a portion of the loop 3312 where the graft bends to form the loop 3312. An implement may be engaged with the suture 3116, which may enable the loop to be passed through the second tunnel 3106 and then through the first tunnel 3102. Further, a set of suture 3318 may be engaged with the free ends of the graft 3314.

After the sleeve 104 is engaged with the second tunnel 3106, the loop 3312 is inserted into the second tunnel 3106 (step 3408), with the bent portion of the loop 3312 facing the second tunnel 3106. The loop 3312 is passed through the tunnels 3106, 3102, such that the portion of the graft 3314 that first entered the second tunnel 3106 is accessible outside the proximal end 3320 of the first tunnel (step 3410). The free ends of the graft 3314 may extend out of the proximal end 3110 of second tunnel 3106.

Thereafter, the at least a portion of the body 10 (in one example, the second flange 14 and retention portion 16) is placed underneath the loop 3312 (step 3412) using an installation instrument 1000, if desired. The suture 3116 is removed from the loop 3312. Subsequently, the loop 3312 is pulled towards the proximal end 3110 of second tunnel 3106 until further movement of the graft 3314 is restricted by the flanges of the body 10 (step 3414). The screw 300 is then engaged with the sleeve 210 (step 3416). The engagement of the screw 300 and the sleeve 210 results in securing the free ends of the graft 3314 at the proximal end 3110 of second tunnel 3106. Excess graft projecting over the head of the screw 310 may be trimmed or otherwise secured.

In the screw and sleeve systems in each instance there may be clearance between the inner walls of the sleeves and the screws to allow the graft to pass through the sleeve and still engage the screw. It is appreciated that various features of the above-described examples can be mixed and matched to form a variety of other combinations and alternatives. The systems described herein need not be limited to ACL graft fixation or sports medicine and knee surgical applications and may be used in instances for alternative functions, including, but not limited to other soft tissue to bone fixation.

Referring to FIG. 28, an insertion tool 1100 may be used to install both the sleeve and screw within the bone tunnel. The tool may be malleted or otherwise forced to drive the sleeve into place and also include a screw interface to engage the central void of the screw to insert the screw within the sleeve.

The components, screws, sleeves and devices disclosed herein may be made from metals, polymers, ceramics, glasses, composite materials, biological materials or tissues, or other biocompatible materials. Different materials may be used for individual components. Different materials may be combined in a single component.

It should be understood that the present system, screw, sleeves, apparatuses, and methods are not intended to be limited to the particular forms disclosed; rather, they are to cover all combinations, modifications, equivalents, and alternatives.

The term "coupled" is defined as connected, although not necessarily directly, and not necessarily mechanically.

The use of the word "a" or "an" when used in conjunction with the term "comprising" in the claims and/or the specification may mean "one," but it is also consistent with the meaning of "one or more" or "at least one." The use of the term "or" in the claims is used to mean "and/or" unless explicitly indicated to refer to alternatives only or the alternative are mutually exclusive, although the disclosure supports a definition that refers to only alternatives and "and/or."

The terms "comprise" (and any form of comprise, such as "comprises" and "comprising"), "have" (and any form of have, such as "has" and "having"), "include" (and any form of include, such as "includes" and "including") and "contain" (and any form of contain, such as "contains" and "containing") are open-ended linking verbs. As a result, a method or device that "comprises," "has," "includes" or "contains" one or more steps or elements, possesses those one or more steps or elements, but is not limited to possessing only those one or more elements. Likewise, a step of a method or an element of a device that "comprises," "has," "includes" or "contains" one or more features, possesses those one or more features, but is not limited to possessing only those one or more features. Furthermore, a device or structure that is configured in a certain way is configured in at least that way, but may also be configured in ways that are not listed.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. As such, the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The invention claimed is:

1. A system for fixing a flexible member between a first member of a patient and a second member of the patient, comprising:

a body comprising:

a retention portion, wherein the retention portion engages the flexible member and is received in a first tunnel defined by the first member; and

a first flange coupled to the retention portion, wherein the first flange engages an outside surface of the first member, wherein the first flange comprises an arm that extends along a circular path and terminates in a free end; and

a screw that at least partially secures at least one strand of the flexible member near a proximal end of a second tunnel defined by the second member.

**2**. The system of claim **1**, wherein the body further comprises a first leg and a second leg, wherein the first leg and the second leg extend from the retention portion, wherein the first flange extends from the first leg, wherein the first leg couples the first flange to the retention portion.

**3**. The system of claim **2**, further comprising a second flange, wherein the second flange extends from the second leg, wherein the second leg couples the second flange to the retention portion opposite the first flange.

**4**. The system of claim **1**, further comprising a second flange coupled to the retention portion opposite the first flange, wherein the second flange engages the outside surface of the first member.

**5**. The system of claim **1**, wherein the screw comprises a head comprising at least one tooth, wherein the tooth forms an interface with the flexible member, wherein the interface prevents the screw from rotating in a removal direction which is opposite to an engagement direction in which the screw is rotated to secure the at least one strand of the flexible member to the second member.

**6**. The system of claim **1**, further comprising a sleeve, wherein the sleeve is received in the second tunnel, and wherein the screw is engaged within the sleeve.

**7**. The system of claim **1**, further comprising a sleeve, wherein the sleeve comprises at least one fin, wherein the fin projects from an outside surface of the sleeve.

**8**. The system of claim **7**, wherein the fin tapers to become flush with the sleeve as the fin advances toward a distal end of the sleeve.

**9**. The system of claim **1**, wherein the first flange comprises an outer profile that is continuously convex.

**10**. A method for fixing a flexible member between a first member of a patient and a second member of the patient, the method comprising:

engaging the flexible member with a retention portion of a body;

tensioning the flexible member, wherein the tensioning results in receiving at least the retention portion of the body inside a first tunnel defined by the first member;

limiting the body from being completely received by the first tunnel as a result of the tensioning, by engaging at least a first flange with an outside surface of the first member, wherein the first flange comprises an arm that extends along a circular path and terminates in a free end; and

at least partially securing at least one strand of the flexible member near a proximal end of a second tunnel defined by the second member.

**11**. The method of claim **10**, wherein engaging the flexible member with the retention portion comprises accommodating at least one loop formed by the flexible member in the retention portion.

**12**. The method of claim **10**, wherein limiting the body from being completely received by the first tunnel comprises engaging at least a second flange with the outside surface of the first member.

**13**. The method of claim **10**, wherein securing the at least one strand of the flexible member comprises pressing the at least one strand of the flexible member against an outside surface of the second member.

**14**. The method of claim **10**, wherein securing the at least one strand of the flexible member comprises:

engaging a screw with the second tunnel through which the at least one strand protrudes; and

creating an interface between a head of the screw and the at least one strand, such that the interface prevents the screw from rotating in a removal direction which is opposite to an engagement direction in which the screw is rotated to engage the screw with the second tunnel.

**15**. The method of claim **10**, wherein securing the at least one strand of the flexible member comprises pressing the at least one strand against an inside surface of a sleeve, wherein the sleeve is at least partially located inside the second tunnel.

**16**. A system for fixing a flexible member between a first member of a patient and a second member of the patient, comprising:

a body comprising:

a retention means for engaging the flexible member; and

an engagement means for engaging the body with an outside surface of the first member, wherein the engagement means comprises an arm that extends along a circular path and terminates in a free end; and

a securing means for securing at least one strand of the flexible member against a wall of a tunnel.

**17**. The system of claim **16**, wherein the retention means is received into the first member.

**18**. The system of claim **16**, wherein the securing means creates an interface with the at least one strand, such that the interface prevents the securing means from rotating in a removal direction which is opposite to an engagement direction in which the securing means is rotated to secure the at least one strand of the flexible member against the wall of the tunnel.

**19**. The system of claim **18**, further comprising an accommodation means, wherein the accommodation means receives at least one strand of the flexible member and the securing means.

**20**. The system of claim **16**, wherein the arm comprises an outer profile that is continuously convex.

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